ASSESSMENT OF TREATMENT RESPONSE TO MICROWAVE ABLATION IN HEPATOCELLULAR CARCINOMA

A THESIS SUBMITTED TO BABA FARID UNIVERSITY OF

HEALTH SCIENCES, FARIDKOT (PUNJAB)

IN THE PARTIAL FULFILLMENT

FOR THE AWARD OF DEGREE OF

DOCTOR OF MEDICINE

IN

RADIO-DIAGNOSIS

(MAY, 2023)

Submitted By

DR. SHIVANI KHANT

DEPARTMENT OF RADIO-DIAGNOSIS
DAYANAND MEDICAL COLLEGE AND HOSPITAL
LUDHIANA, PUNJAB

DECLARATION BY THE CANDIDATE

I hereby declare that the thesis entitled **"ASSESSMENT OF TREATMENT RESPONSE TO MICROWAVE ABLATION IN HEPATOCELLULAR CARCINOMA"** submitted towards partial fulfillment of the requirements for the award of **MD RADIO-DIAGNOSIS** degree to BFUHS is a compilation of original work carried out by me under the supervision of **Dr. Siddharth Prakash,** Associate Professor, Department of Radio-diagnosis, **Dr. Ajit Sood**, Professor & Head, Department of Gastroenterology. **Dr. Chandan Kakkar**, Associate Professor, Department of Radio-diagnosis. No part of this thesis has formed the basis for the award of any degree previously.

_____

DR. SHIVANI KHANT
Department of Radio-diagnosis
Dayanand Medical College & Hospital,
Ludhiana, Punjab

Date:

Place:

CERTIFICATE OF SUPERVISORS

This is to certify that the work incorporated in this thesis entitled **"ASSESSMENT OF TREATMENT RESPONSE TO MICROWAVE ABLATION IN HEPATOCELLULAR CARCINOMA"** has been carried out by **Dr. Shivani Khant** under our direct supervision. The data incorporated in this thesis is original and genuine and has been carried out by the candidate herself.

Signature of Supervisor **Signature of Co-Supervisors**

Dr. Siddharth Prakash
Associate Professor
Department of Radio-diagnosis
DMCH, Ludhiana

Dr. Ajit Sood
Professor & Head
Department of Gastroenterology
DMCH, Ludhiana

Dr. Chandan Kakkar
Associate Professor
Department of Radio-diagnosis
DMCH, Ludhiana

Date:

ENDORSEMENT BY THE HEAD OF THE INSTITUTE

This is to certify that the thesis entitled **"ASSESSMENT OF TREATMENT RESPONSE TO MICROWAVE ABLATION IN HEPATOCELLULAR CARCINOMA"** is a bonafide research work done by **Dr. Shivani Khant** under the supervision of **Dr. Siddharth Prakash,** Associate Professor, Department of Radio-diagnosis, **Dr. Ajit Sood** , Professor & Head, Department of Gastroenterology, **Dr. Chandan Kakkar**, Associate Professor, Department of Radio-diagnosis, in this institution.

Principal

Dr. Sandeep Puri
Principal
DMC&H, Ludhiana

Date:

COPYRIGHT

Declaration by the Candidate

I hereby declare that the Baba Farid University of Heath Sciences, Faridkot, shall have the rights to preserve & use this thesis in print or electronic format for academic/study purpose by the research scholar/students.

Signature

Dr. Shivani Khant
Department of Radio-diagnosis
Dayanand Medical College & Hospital,
Ludhiana, Punjab

Date:

© Baba Farid University of Health Sciences, Faridkot

Dedicated

to

My Family

&

Teachers

ACKNOWLEDGEMENT

It is my sacred duty to pay my debt of gratitude to the Gods, for without their grace and blessings this study would not have been possible.

Words fall short to express the depth of my gratitude to my parents, ***Mr. Rasik kumar H. Khant*** *and* ***Mrs. Binaben R. Khant*** *who have held me when I stumbled, hugged me when I crumpled and showered me with their endless love. I am forever indebted for their eternal selflessness. Special appreciation to my little sister,* ***Hirani R. Khant,*** *whose high spirits and cheer has brightened all my days, and for her deep words of wisdom that are beyond her age.*

I do not have adequate words to express my sense of gratitude to my esteemed teacher and guide, ***Dr. Siddharth Prakash,*** *Associate Professor, Department of Radiodiagnosis, Dayanand Medical College and hospital, Ludhiana, for his ever inspiring guidance and personal supervision. The finest privilege in my professional career has been the opportunity to work under his inspirational guidance.*

I owe my sincere thanks to ***Dr. Kavita Saggar****, Professor and Head of Department of Radiodiagnosis, Dayanand Medical College and hospital, Ludhiana, with all my heart for her overwhelming support, ingenious suggestions and expert guidance throughout my post-graduation period.*

I would extend a special gratitude to my esteemed co-supervisors ***Dr. Ajit Sood,*** *Professor and Head of department of Gastroentrology and* ***Dr. Chandan Kakkar,*** *Professor, department of Radiodiagnosis, Dayanand*

Medical College and hospital, Ludhiana for their endless and consistent support, guidance and encouragement.

This piece of work would have been incomplete without the help and support of my teachers, ***Dr. Archana Ahluwalia, Dr. Kamini Gupta, Dr. Ritu D Galhotra, Dr. Devinderpal Singh Dhanota*** *and* ***Dr. Satwant Khela*** *who encouraged me throughout my post graduation period. My sincere thanks to all my teachers who inspired me for excellence through both constructive criticism and able guidance at every difficult conjec ture.*

A special thank you to the interventional radiology technicians, ***Mr. Deepak Pant, Mr. Saurabh Sharma*** *and* ***Mr. Mohit****, for assisting me with all the data collection, technical support and guidance in making this study possible.*

My family away from home, ***Dr. Jaismine Kohli, Dr. Shaifali Tuteja, Dr. Garima Minhas,*** *and* ***Dr. Philipose A. Puliyelil,*** *I am deeply indebted for their love, care, support and motivation each and every step of the way. This work would truly not have been complete without them.*

My utmost gratitude to my dearest friends, ***Hasmitha K., Madhu Patar, Dr.Disha Prabhu, Dr. Archit Sharma, Dr. Dhaval Solanki, Dr. Aman Gupta, Hena Khant,and Manisha Upadhyaya****, for embracing me with the warmth of love and unconditional support irrespective of the time or distance. A special appreciation to my nieces,* ***Diya*** *and* ***Khushi*** *for always looking up to me, making me believe in myself and encouraging me to do better.*

A sincere appreciation for my batchmates, ***Dr. Angie Garg, Dr. Aarushi Jain, Dr. Navjot Singh, Dr. Navdeep Singh,*** *and* ***Dr. Divyanshu Bhagat*** *for their constant support, encouragement and patience.*

My special thanks go to the entire technical and official staff of Department of Radiodiagnosis, DMCH Ludhiana who provided me with all the valuable help.

I am extremely thankful to all the patients and volunteers who participated in this study. This project would have been unthinkable without their contribution.

I duly acknowledge and appreciate ***Mr. Naveen Bhatia, Mrs. Namita, Mr. Gurjot*** *for their help and incredible display of patience for making this manuscript presentable.*

Dr. Shivani Khant

LIST OF ABBREVIATIONS

HCC	Hepatocellular Carcinoma
NASH	Non-alcoholic Steatohepatitis
CLD	Chronic Liver Disease
US	Ultrasonography
AFP	Alpha Fetoprotein
HCV	Hepatitis C Virus
HBC	Hepatitis B virus
CT	Computed Tomography
MRI	Magnetic Resonance Imaging
LI-RADS	Liver Imaging Reporting and Data System
TACE	Transarterial Chemoembolisation
TARE	Transarterial Radioembolisation
RFA	Radiofrequency Ablation
MWA	Microwave Ablation
BCLC	Barcelona Chronic Clinic Liver Cancer
EASL	European Association for the Study of Liver
ECOG	Eastern Cooperative Oncology Group
AASLD	American Association for the Study of Liver Diseases
CBC	Complete Blood Count
LFT	Liver Function Test

RFT	Renal Function Test
mRECIST	Modified Response Evaluation Criteria In Solid Tumors
LR-TR	LI-RADS Treatment Response
CR	Complete Response
PR	Partial Response
PD	Progressive Disease
SD	Stable disease
p	Probability when the null hypotethesis is true
MELD	Model for End stage Liver Disease

ABSTRACT

Introduction: Hepatocellular carcinoma (HCC) is the most common type of primary liver cancer, and the sixth most common carcinoma globally[1]. The radical cure for HCC is surgical excision or liver transplantation; however, very few cases are diagnosed early, hence the need for tumor ablation therapies arose. As thetechnology and expertise improve, microwave ablation (MWA) is emerging to be moreadvantageous to radiofrequency ablation (RFA) in treating HCC, owing to higher temperatures, shorter ablation time, and less heat sink effect. Based on the aforesaid developments, this study explores the response to MWA on HCC lesions < 5cm, with special attention to lesions between 3-5cm.

Aims and objectives: To assess the immediate and short-term response of hepatocellular carcinoma lesions that are treated with microwave ablation.

Material and method: An observational prospective study of 34 patients (28M; 6F, Age range:45-81years) undergoing MWA for radiologically proven HCC, at the Department of Radiodiagnosis, Dayanand Medical college and Hospital, Ludhiana; during a period of 14 months. An individual lesion's viability post MWA was assessed in accordance to LI-RADS treatment response algorithm, and overall patient's response to treatment by the mRECIST criteria at intervals of 6 weeks and 3 months post ablation.

Results: Out of 34 cases, 3 (8.8%) were BCLC very early stage 0, 17(50%) were early stage A and 14(41.2%) intermediate stage B, with a total of 44 lesions, ranging 0.8-5.0cm. At 6 weeks follow up. 90% of the lesions were LR-TR non-viable, 7.5% LR-TR viable and 2.5% were LT-TR equivocal. The overall patient's response at 6 weeks in terms of mRECIST was: complete response (CR) in 77.4%, progressive disease (PD) in 19.4%, stable disease (SD) in 3.2%. At 3 months follow up, 87.5% and 12.5% of the lesions were LR-TR non-viable and LR-TR viable respectively, with mRECIST CR in 61.3%, PD in 35.5% and SD in 3.2%. 3 deaths were reported, mainly attributed to liver decompensation.

Conclusion: Ablation therapies being minimally invasive, are widely accepted in treating very early and early stage HCC with a good response rate. Moreover, MWA was found to be equally effective in intermediate stage HCC, with an overall survival rate of 91.2% in this study group. Immediate major complication was intra-tumoral bleed.

Keywords: Hepatocellular carcinoma, microwave ablation, locoregional therapies, LI-RADS, mRECIST

TABLE OF CONTENTS

S.NO.	TOPIC	PAGES
I	INTRODUCTION	1-11
II	AIMS AND OBJECTIVES	12
III	REVIEW OF LITERATURE	13-19
IV	MATERIALS AND METHODS	20-25
V	OBSERVATIONS AND RESULTS	26-61
VI	DISCUSSION	62-67
VII	LIMITATIONS	68
VIII	SUMMARY AND CONCLUSIONS	69
IX	BIBLIOGRAPHY	70-76

APPENDICES–I

- PROFORMA
- MASTER CHART

APPENDICES–II

- APPROVAL LETTER OF THESIS PLAN
- THESIS PLAN

LIST OF TABLES

TABLE NO.	TITLE	PAGE NO.
1	LI-RADS CT/MRI criteria	2
2	Child-Pugh classification for severity of cirrhosis	7
3	LI-RADS Treatment Response (LR-TR)	10
4	mRECIST criteria for HCC[	10
5	MRI Acquisition parameters	23
6	Age wise distribution of patients with HCC who underwent MWA	26
7	Sex wise distribution of HCC patients who underwent MWA	27
8	Risk factor associated with cirrhosis	28
9	Alcohol, smoking and opium users among the patients	29
10	Child-Pugh classification of the cases	30
11	MELD scores of the patients	31
12	BCLC stages of the cases	33
13	Number of lesions per patient	34
14	Segmental distribution of the lesions identified on imaging	35
15	Number of lesions as per the size	37
16	Number of lesions beyond 3.0cm and less than 5.0cm	38
17	LI-RADS diagnosis of the lesions	39
18	Time taken to ablate each lesion	40
19	Average MWA protocol used for the average size of lesion.	41
20	Ablation zone applied for each set of lesions according to their size	42
21	Mean size of lesion compared to mean MWA zone	43

22	Spearman's rho comparing the size of the lesion and the MWA zone applied	44
23	LI-RADS Treatment Response of the lesions at 6 weeks follow up	45
24	LI-RADS Treatment response at 6 weeks of lesions ≥ 3.0 cm (beyond the BCLC guidelines)	47
25	Overall patients' response to MWA at 6 weeks follow up by mRECIST	49
26	mRECIST at 6weeks compared to the number of lesions per patient	51
27	LI-RADS Treatment Response of the lesions at 3 months follow up	53
28	LI-RADS Treatment response at 3 months of lesions ≥ 3.0 cm (beyond the BCLC guidelines)	54
29	Overall patients' response to MWA at 3 months follow up by mRECIST	56
30	mRECIST at 3 months compared to the number of lesions per patient	58
31	Progressive disease on mRECIST at follow ups	60
32	Outcome of the patients in terms of survival or death	61

LIST OF FIGURES

FIGURE NO.	TITLE	PAGE NO.
1	Modified BCLC staging and treatment strategy (Adapted from the EASL guidelines)	6
2	LI-RADS Treatment Response Algorithm	11
3	Age wise distribution of patients with HCC who underwent MWA	26
4	Sex wise distribution of HCC patients who underwent MWA	27
5	Risk factor associated with cirrhosis	28
6	Alcohol, smoking and opium users among the patients	29
7	Child-Pugh classification of the cases	30
8	MELD scores of the patients	32
9	BCLC stages of the cases	33
10	Number of lesions per patient	34
11	Segmental distribution of the lesions identified on imaging	36
12	Number of lesions as per the size	37
13	Number of lesions beyond 3.0cm and less than 5.0cm	38
14	LI-RADS diagnosis of the lesions	39
15	Time taken to ablate each lesion	40
16	Average MWA protocol used for the average size of lesion.	41
17	Ablation zone applied for each set of lesions according to their size	42
18	Mean size of lesion compared to mean MWA zone	43
19	Spearman’s rho comparing the size of the lesion and the MWA zone applied	44

20	LI-RADS Treatment Response of the lesions at 6 weeks follow up	45
21	LI-RADS Treatment response at 6 weeks of lesions ≥ 3.0 cm (beyond the BCLC guidelines)	48
22	Overall patients' response to MWA at 6 weeks follow up by mRECIST	49
23	mRECIST at 6weeks compared to the number of lesions per patient	52
24	LI-RADS Treatment Response of the lesions at 3 months follow up	53
25	LI-RADS Treatment response at 3 months of lesions ≥ 3.0 cm (beyond the BCLC guidelines)	55
26	Overall patients' response to MWA at 3 months follow up by mRECIST	56
27	mRECIST at 3 months compared to the number of lesions per patient	59
28	Progressive disease on mRECIST at follow ups	60
29	Outcome of the patients in terms of survival or death	61

LIST OF PICTURES

PICTURE NO.	TITLE
1	Case one- pre-ablation CT triphasic axial images
2	Case one-Post ablation CECT axial images
3	Case two – pre-ablation multiphasic MR axial images
4	Case two - post-ablation axial CT triphasic images on follow up
5	Case three - pre-ablation CT triphasic axial images
6	Case three- post ablation follow up imaging

INTRODUCTION

BACKGROUND

Hepatocellular carcinoma (HCC) is the sixth most common malignancy and the third most common cause of cancer related death.[1] HCC is an epithelial tumor composed of cells with similar characteristics of normal hepatocytes.

The most important risk factor for developing HCC is cirrhosis. What percentage of cirrhotic patients develop HCC is further dependent on multiple other factors, such as the cause (Hepatitis B or C virus, alcohol), severity (decompensated/compensated cirrhosis), or sex (male/female). Patients without cirrhosis, may also carry a risk of developing HCC, especially those with chronic liver inflammation (chronic hepatitis C / B virus infection, chronic alcoholics), Non-alcoholic steatohepatitis (NASH), high dietary intake of aflatoxins, or a family history of HCC.[2]

The prognosis of patients with HCC is essentially dependent on the stage at which the tumor is first diagnosed. HCC does not cause any symptoms any different from those of the underlying liver disease and hence, it is unfortunately detected at a much later stage with a dismal prognosis. However, patients in whom the tumor is detected at an early stage, may be benefited by life-prolonging, probably curative available treatments.

The earliest detection of HCC is therefore crucial for its timely management; in turn pressing on the need for active surveillance of patients with chronic liver disease (CLD). Most surveillance guidelines recommend ultrasonography (US) as the primary imaging test for surveillance and a few suggest the ancillary use of serum biomarkers.[3] These include α-fetoprotein (AFP), Protein induced by vitamin K absence-II (*PIVKA-II*) and an isoform of ALP called as AFP-L3.

For imaging HCC, CT liver (triphasic) protocol is used, wherein unenhanced, pre-contrast images are acquired first and then, three

phases (late arterial, portal- venous, delayed) are acquired after contrast administration. The extracellular contrast agent used helps in the diagnosis of HCC by depicting the enhancement based on the physiologic changes that occur during hepatocarcinogenesis in the vascularity of a dysplastic nodule. On Magnetic resonance imaging (MRI), multiple sequences are acquired prior to and after contrast administration at multiple intervals.

CHARACTERISATION OF THE LIVER LESION

The CT/MRI diagnostic algorithm by Liver Imaging Reporting and Data System (LI-RADS) version 2018 helps in characterising hepatic lesions without the need of pathological correlation, which is elaborated in Table 1.[4]

Table 1: LI-RADS CT/MRI criteria[4]

Diagnostic category	Description	CT/MR criteria
LR-NC: Noncategorizable	Owing to image omission or degradation, lesion cannot be clearly categorised	
LR-1: Definitely benign	Absolute certainty that a lesion is not malignant	Examples include: cyst, hemangioma, perfusion defects, fat sparing/deposition, etc
LR-2: Probably benign	High probability that a lesion is not malignant, but not absolutely certain	Examples include: cyst, hemangioma, perfusion defects, fat sparing/deposition, etc Size <20mm. No major features/ LR-M features or ancillary features

LR-3: Intermediate probability of malignancy	Moderate probability that a lesion may or may not be malignant	**Nonrim arterial phase hyperenhancement AND:** <20mm with no other major feature **Arterial pahse hypo/iso-enhancement AND:** <20mm +/- 1 other major feature **OR** ≥20mm with no other major features
LR-4: Probably HCC	High probability of the lesion being HCC, but not absolutely certain	**Nonrim arterial phase hyperenhancement AND:** <10 mm +/- other major feature **OR** 10-19mm + capsule and no other major feature **OR** ≥20mm with no other major features **Arterial phase hypo/iso-enhancementAND** <20mm + ≥ 2 other major features **OR** ≥20mm + ≥ 1 other major feature
LR-5: Definitely HCC	Absolutely certain that the lesion is HCC	**Nonrim arterial phase hyperenhancement AND:** 10-19mm + non peripheral washout with no other major feature **OR** 10-19mm + ≥50% size increase in ≤6months with no other major feature **OR** ≥20mm + ≥ 1 other major feature

LR-TIV: Malignancy with tumor in vein	Absolutely certain that there is a malignancy with tumor in vein	Definite enhancing soft tissue in vein +/- parenchymal mass
LR-M: Probably/ definitely malignant, not specifically HCC	Absolutely certain that an observation is malignant, but its features are not specific to HCC. This raises a high possibility of a malignant lesion other than HCC, but does not exclude HCC as a possibility.	**Targetoid mass:** Rim arterial phase hyperenhancement Peripheral washout Delayed central enhancement Targetoid diffusion restriction Targetoid transitional/hepatobiliary phase signal intensity **Nontargetoid mass not meeting LR-5 without TIV, with at least 1 of the following:** Infiltrative appearance Marked diffusion restriction Necrosis/severe ischemia Other feather suggesting non-HCC malignancy

Major features include: Enhancing “capsule”, non-peripheral “washout” and threshold growth.[4]

Ancillary features favoring malignancy and not HCC in particular include: discrete nodule visible on ultrasound, subthreshold growth, restricted diffusion, mild-moderate T2 hyperintensity, corona

enhancement fat/iron sparing in solid mass, or transitional / hepatobiliary phase hypointensity.[5]

Ancillary features favoring HCC in particular include: non-enhancing “capsule”, nodule-in-nodule, mosaic architecture, blood products in mass or fat in mass (more than the adjacent liver).[5]

Ancillary features favoring benignity include: stable size in more than 2 years, size reduction, parallels the blood pool, undistorted vasculature, more iron in mass than the liver, markedly hyperintense on T2 or isointense in hepatobiliary phase.[5]

TREATMENT PROTOCOL AND STRATEGY

The treatment protocol to be used in HCC is dependent on many factors such as, tumor characteristics (size, location, number), background liver cirrhosis, vascular invasion, liver function, presence of metastasis, other medical comorbidities, availability of resources, and the cost versus affordability of the treatment.[6]

Multiple modalities are available for treatment of unresectable liver tumors. An interventional radiologist, may use a transarterial approach or thermal ablation technique for the treatment of the lesions. For example, transarterial embolization (TAE), Transarterial chemoembolization (TACE), transarterial radioembolization (TARE) or ablation therapies such as radiofrequency ablation (RFA) or microwave ablation (MWA).[7]

The Barcelona Clinic Liver Cancer (BCLC) staging system and treatment strategy classifies patients into five stages (0, A, B, C, and D) according to pre-established prognostic variables, and recommends a treatment strategy. Ablation, one of the locoregional therapies for HCC is recommended by the European Association for the study of Liver (EASL) for very early HCC (BCLC stage 0) and early HCC (BCLC stage A), when the patient is not a good surgical or transplant candidate.[8]An adaptation of the modified BCLC staging and treatment strategy is illustrated in Figure 1.

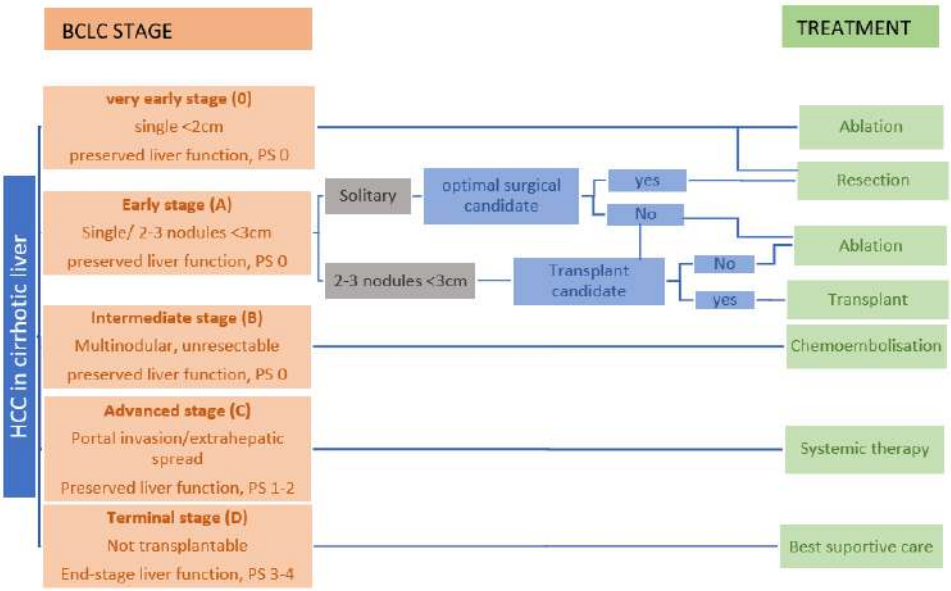


Figure 1: Modified BCLC staging and treatment strategy (Adapted from the EASL guidelines)[8] "PS" refers to performance status by Eastern Cooperative Oncology Group (ECOG) graded from PS0 to PS4, "preserved liver function" refers to Child-Pugh class A / B, "end-stage liver function" refers to Child-Pugh class C

The ECOG performance status of a patient is a scale used to assess the patient's level of function and capability of self-care. It is scored from PS0 in which a patient is fully active and able to carry on all pre-disease activities, to a scale of PS5 which means death. PS1 refers to a patient restricted in strenuous physical activities, but ambulatory to carry out light house chores and office work. PS2 patients are ambulatory but cannot carry out any work. Patient scored as PS3 is capable of only limited self -care and is mostly confined to the bed or chair, whereas a score of PS4 means the patient is completely disabled and totally confined to the bed or chair.[9]

Child-Pugh scoring system is a prognostic indicator for liver function used the assessment of severity of the disease in CLD and cirrhotic patients, which is elaborated in Table 2.

Table 2: Child-Pugh classification for severity of cirrhosis [10]

CLINICAL AND LAB PARAMETER	POINTS		
	1	2	3
Albumin (g/dL)	>3.5	2.8-3.5	<2.8
Bilirubin (mg/dL)	<2	2-3	>3
Ascites	Absent	Mild-moderate	Severe
Encephalopathy	None	Mild-moderate	Severe
Prothrombin time/ International Normalised Ratio (PT/INR)	<1.7	1.8-2.3	>2.3
CLASS A = 5-6 points: least severe disease **CLASS B = 7-9 points: moderately severe disease** **CLASS C = 10-15 points most severe disease**			

WHAT IS MICROWAVE ABLATION?

Tumor ablation is defined as a direct application of non-energy (chemical) or energy based (thermal and non-thermal) modalities to eradicate or destroy a tumour either through heat or cold or non-thermal mechanisms. The most commonly used thermal ablation techniques include radiofrequency ablation (RFA) and microwave ablation (MWA). These thermal modalities use applicators such as electrodes, probes and antennae using imaging guidance such as ultrasound, CT or MRI for percutaneous approaches to “burn” the lesions.[11]

MWA devices consist of 3 parts, the generator, a flexible cable, and an electrode/ probe. Both RFA and MWA are thermal ablation techniques which use electromagnetic energy and induce water molecules to

rotate. Adequate heat is generated so as to cause coagulative necrosis. Usually, the heat generated through microwave is dissipated centrifugally around the tip of the probe. The tumour cells can be destroyed effectively by the denaturation of intracellular proteins and cell membranes through the dissolution and melting of the lipid bi-layer, after enough heat has been generated around the probe tip.[12] Coagulation necrosis will begin immediately at temperature ranging from 60°C to 100°C. Beyond 110°C vaporization and carbonisation occurs, which should be avoided.[11]

Each generator has a capacity to produce different powers, for example 45-100 W at a frequency of 915 MHz or 2450 MHz, depending on the device type.[12] Each MWA device can be set for a particular burn protocol, depending on the size of each lesion/ targeted ablation zone. For example, setting a power of 100W for 5 minutes to achieve an ablation zone of 3.9x3.4cm. These burn protocols are usually provided by the MWA device companies.

INDICATION FOR MWA

Ablation is recommended as the first-line treatment for patients who are not fit for liver transplantation, and who are staged at BCLC very early stage 0 and Early stage A.

Likewise, the American Association for the Study of Liver Diseases (AASLD) also recommends locoregional therapy the for early-stage HCCs (≤3 cm in size and ≤3 lesions) or early-stage HCCs (≤2 cm) with complications including portal hypertension.[13]

CONTRAINDICATIONS FOR MWA

Absolute contraindications include: Total tumor volume of 70% or more of the liver volume, numerous tumor nodules, metastatic disease/ extrahepatic spread, signs of liver failure (massive ascites,

encephalopathy) or other organ failure, deranged blood coagulation profile (platelet count <30,000/mm^3), or active infection/inflammation elsewhere in the body.[13]

PATIENT PREPARATION

A multidisciplinary opinion should be taken to discuss each case before the procedure including and not limited to a hepatologist, hepatobiliary surgeon, oncologist, and anaesthesiologist. A written informed consent signed by the patient, having being explained the procedure in his/her own language, the benefits, risks and complications of MWA, alternative therapies available and the cost of the procedure. Preprocedural work-up must include the routine blood tests like complete blood count (CBC), liver function tests (LFT), renal function tests (RFT), and coagulation tests. Pre-ablation CT /MRI not more than one month old.

Fasting status of the patient for least 6 hours prior to the procedure. The ablation may be carried out under local anaesthesia and analgosedation, for an outpatient procedure. A one day admission is usually preferred and practiced for the procedure, especially if done under general anaesthesia.[14]

POST PROCEDURAL IMAGING

Because microscopic foci of residual disease cannot be seen with normal imaging, postprocedural imaging data can be used as a rough indicator of the effectiveness of ablation therapy.

The assessment of ablation response on each ablated lesion may be done using the LI-RADS Treatment Response algorithm (LI-RADS-TR)[15], (Table 3) and/or the modified Response Evaluation Criteria In Solid Tumors (mRECIST)[16] to evaluate the overall outcome (Table 4).

Table 3: LI-RADS Treatment Response (LR-TR)[15]

TREATMENT RESPONSE CATEGORY		**CRITERIA**
LR-TR Nonviable	Treated, probably or definitely not viable	No lesional enhancement OR treatment specific expected enhancement pattern.
LR-TR Equivocal	Treated, equivocally viable	Enhancement atypical for treatment specific expected enhancement pattern and does not meet criteria for probably or definitely viable.
LR-TR Viable	Treated, probably or definitely viable	Nodular, masslike, or thick irregular tissue in or along the treated lesion with any of the following: • Arterial phase hyperenhancement OR • Washout appearance OR • Enhancement similar to pretreatment.

Table 4: mRECIST criteria for HCC[16]

TREATMENT RESPONSE CATEGORY	CRITERIA
Complete Response (CR)	Disappearance of the targeted lesions
Partial Response (PR)	At least a 30% decrease in the sum of

	diameters of viable target lesions
Progressive Disease (PD)	20% increase in the sum of the longest diameter of the targeted lesion, or the appearance of one or more new lesions
Stable Disease (SD)	Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease

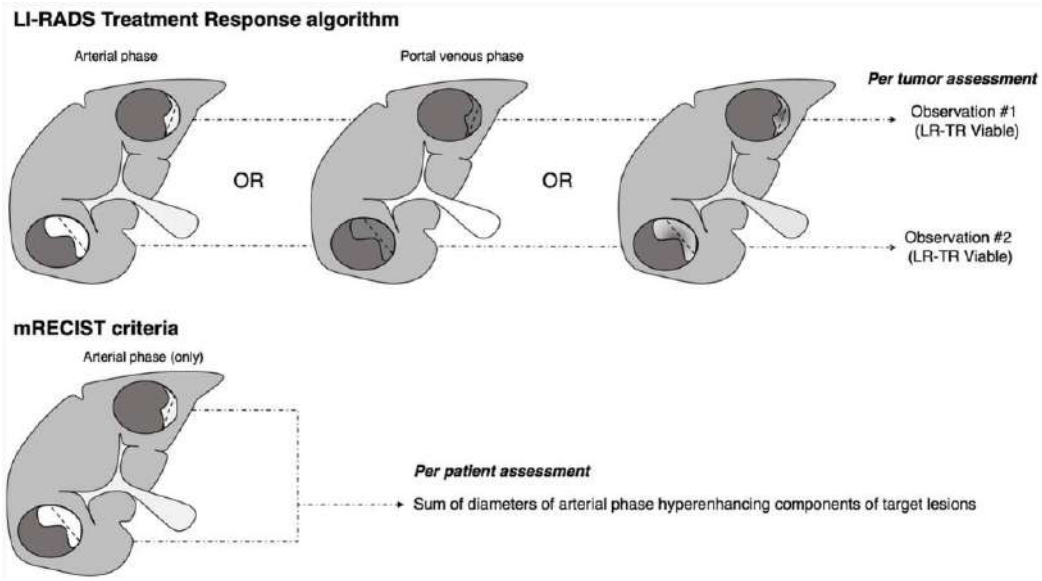


Figure 2: Method of assessing the viability of ablated lesion using LR-TR and mRECIST.[17] In LR-TR, viable tumor is defined as having a nodular or thick rim residual arterial phase hyperenhancement (APHE), or portal/venous washout or enhancement similar to pre-ablation tumor characteristics in any phase of imaging. In mRECIST, residual APHE is considered viable. In both, the longest diameter of the enhancement is measured.

AIM AND OBJECTIVES

1. To assess the immediate and short-term response of hepatocellular carcinoma lesions that are treated with microwave ablation.

REVIEW OF LITERATURE

Percutaneous thermal ablation; RFA and MWA, are both recommended and very well established locoregional therapies for small HCCs falling under BCLC very early stage(0) and early stage (A) HCCs. These being minimally invasive procedures makes them more sought out to eliminate or reduce the tumor viability and prolong the disease progression and ultimately extend overall survival. Although they both use the same principle of 'heat' they each have their own merits and demerits.

SURGICAL RESECTION IN COMPARISON TO ABLATION THERAPIES

Ablation therapy is gaining popularity among interventional radiologists and is considered a potential first-line therapy for small HCC lesions. Radiofrequency ablation (RFA) uses electric current in the RF range, delivered through a monopolar or multipolar electrodes and produces heat based cytotoxicity to the tissue in contact. Microwave ablation (MWA) on the other hand, uses electromagnetic energy to heat the surrounding tissue, which is less susceptible to the cooling effect of surrounding blood vessels.[8]

Many studies show comparative results in treatment of early HCC with surgical resection and thermal ablation. A study by Lü et al. in 2006, compared the effects of surgical resection to that of ablation in 105 patients. 54 of whom were randomly allocated surgical resection and 51 allocated ultrasound guided percutaneous tumor ablation. The study demonstrated a complete tumor elimination rate of 100% with surgical resection, and 94.7% with RFA/MWA and reported a local recurrence rate of 0 in both of the techniques.[18]

In 2006, a similar study by Chen et al. compared the results of percutaneous tumor ablation with surgical resection for solitary and small HCC (≤5cm) in 180 patients. 90 of who were randomised to receive ablation therapy and the other half, were to undergo surgical

resection of one Couinaud liver segment. They also reported no statistically significant difference in overall survival in those treated for a solitary tumor ≤5cm with either surgical resection or RFA/MWA. The 1-, 2-, 3- and 4- year overall survival rates were 93.3%, 82.3%, 73.4%, 64.0% and 95.8%, 82.1%, 71.4%, 67.9% for resection and ablation respectively.[19]

In a study by N. Bhardwaj et al in the year 2010, the different ablation modalities in the treatment of HCC were compared. RFA had limitations due to the consequences of high tissue temperatures around the probe. The production of electrically insulating gas between the electrode and tissue by the vaporizing tissue fluid, caused by the rising temperatures above 100°C led to the increase in tissue impedance, resulting in significant reduction in the flow of current. Hence only tissue immediately adjacent to the applicator is heated by ionic agitation, whereas the rest of the surrounding tissue is heated by thermal conduction from this central zone. Ablation of larger tumors with RFA therefore became challenging. Lesions around high flowing blood vessels would experience a cooling effect, disrupting the thermal conduction, making it less efficient. This is known as the 'heat-sink effect' of RFA.[20]

In 2013, Jianmin Ding et al compared the safety and efficacy of MWA and RFA in the treatment of HCC in keeping with the Milan criteria. Complete ablation rates for RFA and MWA (P = 1.000) were reported as 99.0% and 98.5% respectively. Local recurrence rates for RFA and MWA (P = 0.127) were 5.2% and 10.9% respectively. Disease-free survival rates in the RFA group at 1, 2, 3, and 4 years were 80.3%, 61.8%, 39.5%, and 19.0%. while 75.0%, 59.4%, 32.1%, and 16.1% reported in the MWA group, respectively (P = 0.376). In conclusion, they reported a statistically insignificant difference in the clinical value of RFA and MWA in treating HCC when conforming to the Milan criteria.[21]

A Cochrane review was done in the year 2013 comparing effects of ablation and surgical resection in early HCC by conducting four trials in 574 patients. There was no significant difference in in mortality rates between the two treatment modalities. The authors reported more serious adverse events in the resection group compared to the ablation group, but reported a lower recurrence rate of HCC in the resection group than in the ablation group. Length of hospital stay was found to be more in the surgically treated patients. On analysing different literature materials, ablation was found by EASL to be the most cost-effective therapy for very early HCC and early HCC.[22]

ABLATION STUDIES WITH REGARD TO SIZE OF TUMOR

MWA has started to gain more acceptance with recent advances in technology, as it gives a wider ablation zone in a shorter time compared to RFA, with a further advantage of less heat sink effect.

A study in 2007 by Kuang et al. reported complete ablation response rates of 94% in small (≤3.0cm), 91% in intermediate (3.1cm-5.0cm) and 92% in large (5.1cm-8.0cm) sized liver tumors in 90 patients with primary or metastatic liver cancers treated with MWA. They also reported a significant difference in the local tumor progression rate between cirrhotic and non-cirrhotic patients, in a follow-up period of 17.4 months.[23]

A retrospective study in China that spanned over 13 years was conducted by Liang P. et al with results published in 2007, reported survival rates of 1007 patients with primary liver cancer as 91.2% and 59.8% at 1- year and 5-year post MWA. The study documented a 5-year survival rate ranging from 29% to 68.6% for tumors size > 5.0cm treated with MWA.[24]

A study by Yin et al. in 2009, similarly reported complete response rates of tumor sizes 3.0-5.0cm to be 95.4% (in 84 out of 88) and tumor sizes 5.0cm-7.0cm to be 80% (in 16 out of 20). On using both RFA and MWA to ablate HCC tumors sized 3.0cm-7.0cm, overall survival rates

at 1-, 2-, 3-, and 5-year as 76%, 47%, 31% and 15% were reported respectively. Median survival rates for RFA was 19 months compared to 30.3 months of MWA treated patients. Treatment of HCC between 3-7cm by thermal ablation was concluded to be efficient and safe, with good local tumor control and long term success rates.[25]

A multicenteric Italian study by Livraghi et al. in 2011 performed MWA on 736 patients with hepatic tumors ranging from 0.5 - 10.0 cm, proved MWA as a high safety procedure with little major complication rates and zero deaths reported.[26]

Another multicentric study in Italy by Antonio et al. in 2011 studied long-term outcomes of 215 patients with intermediate stage HCC treated with MWA. They reported complete ablation rates of 100%, 89%, and 92% in lesions sized 1.5-3.0cm, >3.0-5.0cm and >5.0-8.0cm respectively.[27]

In 2013, Liu et al. reported complete response rate of 94.2% for 3cm-5cm tumor sizes in 49 patients out of 52, and 75% for tumors sized 5cm-8cm in 21 patients out of 28. Complete ablation rates were hence reported to be significantly higher in patients with lesions between 3-5cm than in those measuring 5-8cm.[28]

In 2017 in a study by Wei H et al., MWA was used to treat 19 patients who had tumors that ranged in size from 3cm to 9.5cm. The study followed up the patients at 1-, 3-, 6- months post ablation, and evaluated the response using mRECIST criteria. From a total of 23 tumors, 8 tumors had Complete Response (CR), 10 tumors showed Partial Response (PR), 3 tumors had Stable Disease (SD), and 2 tumors had Progressive Disease (PD). The study reported an overall survival rate of 94.4%, 94.4% and 85.7% for 6- month, 1-year and 2-year on follow up respectively. The study reported a survival benefit of years for tumors sized ≥3.0cm that were treated with MWA.[29]

Another study in 2017 by Ma S. et al. retrospectively analysed 433 HCC patients, with lesions ≤ 10.0cm who received MWA. The study

reported the efficacy of MWA after one month interval of the treatment, and reported the following outcomes: initial complete ablation rate of 94.9 % in 411/433 patients. Repeat MWA was given to 22 incomplete ablation patients and the overall complete ablation rate increased to 98.6% in 427 out of the 433 patients. The study reported a cumulative overall survival rate of 83.5%, 66.1%, and 58.7 % at 1-, 2-, and 3-year interval, respectively. The study concluded by expressing good tolerance of MWA in HCC patients, and proving high complete ablation rates in its sample group. The study also expressed, multiple tumor number, tumor size >5cm, and serum AFP level >400ng/ml to be significant poor prognostic indicators of progression-free survival.[30]

In 2019, Darweesh SK and Gad AA, conducted a study on effects of MWA on HCV- related HCC on fifty-nine patients. They reported a complete ablation in 57 (96.6%) patients, with minor complication rate of 3.3%. Furthermore, the study showed no significant difference in the ablation rates when tumor sizes <3.0 cm and 3.0-5.0cm were compared. The study documented survival rates of 95.4% at 1 year and 69% at 2 years interval, concluding that MWA was safe and effective in treating HCV related HCC with a good survival rate.[31]

MWA IN DIFFICULT ANATOMICAL SITES

An ablation zone of at least 5mm wider than the tumor margin is considered ideal for best local tumor control.[32] However an equal margin of a minimum of 5mm, may be challenging to achieve due to topographical factors such as close proximity to a major vessel, diaphragm, gall bladder, or lesions in subcapsular location. These are hence termed as ‘difficult anatomical sites’ or ‘challenging anatomical sites’.[33]

A study by Filippiadis DK et al. in 2017, conducted to analyse the efficacy of MWA in HCC lesions sized 1.4 – 5.0cm, at difficult anatomical sites, such as tumors in close proximity to the heart, or at hilum of the liver, in the hepatic dome, or in subcapsular location. The study reported a 2-year and 5-year survival rate of 92.3% and 72.11%,

respectively. In conclusion, they documented high efficacy and safety rates of MWA in difficult anatomical sites in lesions measuring <5.0 cm.[34]

In 2019, Ahmad F Soliman et al. conducted a study in 88 patients with HCC in difficult anatomical sites such as lesions lying <5cm from the gall bladder, major vessel or capsule. The ablation rates were 75%, 87.5% and 100% for lesions in perivascular (in 12/88 patients), subcapsular location (in 32/88patients) and those close to the gall bladder (in 2/88 patients) respectively. MWA was deemed just as efficient and safe for treating HCC in challenging anatomical areas as it is for ordinary sites.[35]

In 2020, Chao An et al. analysed a total of 489 HCC patients who underwent MWA and compared the effectiveness, complications and survival outcomes in those with challenging anatomical site lesions and those with non-challenging sites among them. They reported similar results in those with difficult sites such as proximity to gall bladder, major vessels, diaphragm, hepatic hilum and subcapsular location to those with non-challenging sites. The success and survival rates of these lesions were concluded to be on par with those of non-challenging sites.[36]

LIVER TRANSPLANTATION IN HCC

Liver transplantation is the absolute cure for HCC which is limited to the liver, with no vascular invasion and no distant metastasis. Owing to the competition between liver transplant candidates (those with or without HCC), for the scarce resources, the need for a strong allocation policy that defines eligibility and waiting-list prioritization over the non-HCC patients was a necessity.[37]

The Milan criteria is a set of criteria used to assess suitability of HCC patients for liver transplantation. It includes patients with a single tumor ≤ 5.0cm or maximum of three tumors, each with a diameter of ≤3.0cm, no extra-hepatic involvement and no major vascular invasion. Under

Model for End-Stage Liver Disease (MELD) allocation, HCC candidates must meet this criteria.[38]

A study by Loannou. et al. in 2008, examined the impact of MELD allocation system in liver transplantation for HCC and predictors of survival. They reported a 6-fold increase in the proportion of transplantation patients with HCC, after adoption of MELD in the years 2002-2007 (26%) compared to the pre-MELD era patients in 1997-2002 (4.6%). They also concluded that a MELD score of ≥20 and AFP ≥ 455ng/ml as most important predictors of poor post-transplantation survival.[39]

In 2012, Pratima Sharma et al. examined the factors associated with post liver transplantation recurrence of HCC in the MELD era. The median MELD score was 13, with 94% candidates meeting the Milan criteria. They reported HCC recurrence in 18% of the post-transplant patients after 2.1 median years. They associated this high recurrence rate to number of lesions and size at the time of transplantation, and older donor age.[40]

MATERIAL AND METHODS

SOURCE OF DATA

The study included patients diagnosed with HCC in the Department of Radiology in Dayanand Medical College and Hospital, Ludhiana who underwent microwave ablation for their treatment; over a period of 14 months, from February 2021 to June 2022.

METHOD OF COLLECTION OF DATA

Written consent was obtained from each patient willing to participate in the study, after having explained the procedure in his/her vernacular language. A detailed clinical history was documented of each patient's clinical profile, with special attention to the age of presentation, gender, alcohol history, background of non-alcoholic fatty liver disease (NAFLD), liver cirrhosis, history of Hepatitis C and B virus infection. The diagnosis of HCC was based on contrast enhanced CT / MRI triphasic imaging evidence (LI-RADS IV or higher) with or without raised Alpha Fetoprotein levels (AFP). None of the patients underwent tissue biopsy for histopathological diagnosis of HCC. The patients who were diagnosed with HCC and underwent MWA as the therapeutic procedure of choice, were included in this study.

INCLUSION CRITERIA:

The HCC patients eligible for MWA and thence this study, were as follows:

- No more than 3 tumors in each individual patient
- Each tumor size ≤ 5.0cm
- Liver function status at Child-Pugh class A or class B
- Good coagulation profile, with International Normalized Ratio (INR) <1.5 and platelet count of >50,000/mm^3.

EXCLUSION CRITERIA:

The following patients were excluded from the study:

- Tumor size > 5.0 cm
- Presence of vascular invasion, distant metastasis, and lymph node involvement.
- Liver function status at Child-Pugh class C
- Insufficient patient data

CT IMAGING PROTOCOL

Scans were performed on SIEMENS 128 slice CT scan machine, with patient in supine position in quite respiration. Intravenous non-ionic water-soluble contrast (1.5mg/kg body weight at the rate of 3ml/sec) was injected after attaining a plain study.

- Images are acquired at multiple phases:

  Late arterial phase: taken after bolus tracking,

  venous phase obtained 30 seconds after arterial phase,

  Delayed phase taken 4.5mins after venous phase.
- Scan area of interest: dome of diaphragm to pubic symphysis.
- Direction of scan: cranio-caudal
- Collimation: 128*0.6mm
- Pitch: 0.8
- Reconstructed slice thickness: 1mm
- FOV (field of view): 400-750mm
- Current: 175mAS
- Voltage: 120kV

MR IMAGING PROTOCOL

Multiple phase study was performed on SIEMENS MAGNETOM SKYRA48 CHANNEL 3 Tesla MRI with intravenous gadolinium based contrast (0.1ml/kg body weight). Phases were acquired as follows, with acquisition parameters as shown in Table 5

Arterial phase: taken after bolus tracking,

Portal phase: 13 seconds after arterial phase

venous phase obtained 16 seconds after portal phase,

Delayed phase taken 5 minutes after venous phase, and another after 1 hour.

Table 5: MRI Acquisition parameters

	TR	TE	FOV (R)	FOV (P)	No. SLICE	SLICE THICKNESS	GAP	FLIP ANGLE	FAT SAT	MATRIX	FLOW COMP	PHASE ENC	ORIENTATION
T2 haste axial	2000ms	91	350	78.1 %	30	5mm	2.5mm	160	None	200*320	NO	AP	Transverse
T2 Fat sat	2000ms	91	350	78.1 %	30	5mm	2.5mm	160	SPAIR	200*320	NO	AP	Transverse
T2 haste coronal	2000ms	91	350	100 %	35	5mm	0.5mm	160	None	288*320	NO	R>>L	Coronal
Diffusion	5700ms	48	380	80.6 %	30	5mm	2.5mm		SPAIR	108*134		AP	Transverse
T1 vibe	4.34m	1.34,	380	81.3	72	3mm	1.1m	9	None	182*32	NO	AP	Transverse

in-out phase	s	2.76		%			m			0			
T1 vibe fat sat	3.31ms	1.3ms	380mm	81.3%	72	3mm	1.1mm	9	SPAIR	182*320	NO	AP	Transverse
Arterial T1 vibe fat sat	3.31ms	1.3ms	380mm	81.3%	72	3mm	1.1mm	9	SPAIR	182*320	NO	AP	Transverse
PortalT1 vibe fat sat	3.31ms	1.3ms	380mm	81.3%	72	3mm	1.1mm	9	SPAIR	182*320	NO	AP	Transverse
Venous T1vibe fat sat	3.31ms	1.3ms	380mm	81.3%	72	3mm	1.1mm	9	SPAIR	182*320	NO	AP	Transverse
Delayed T1vibe fat sat	3.31ms	1.3ms	380mm	81.3%	72	3mm	1.1mm	9	SPAIR	182*320	NO	AP	Transverse

ULTRASOUND GUIDED PERCUTANEOUS MWA PROCEDURE

The microwave ablation was performed using the Medtronic EmprintTM ablation system with ThermosphereTM technology, under ultrasound guidance using SONOSITEEdge II ultrasound machine.

OUTCOME

Contrast enhanced CT/MRI was performed on patients treated with MWA for HCC at 6 weeks and 3 months post microwave ablation to evaluate the therapeutic response. Viability of individual lesions post MWA was assessed in accordance to the LI-RADS treatment response algorithm and overall patient's response to the ablation, was assessed in accordance to the mRECIST criteria.

STATISTICAL ANALYSIS:

Data was be described in terms of range; mean ±standard deviation (± SD), frequencies (number of cases/ lesions) and relative frequencies (percentages) as appropriate. All statistical calculations were done using (Statistical Package for the Social Science) SPSS 21version (SPSS Inc., Chicago, IL, USA) statistical program for Microsoft Windows.

OBSERVATION AND RESULTS

1) DEMOGRAPHIC DATA

AGE WISE DISTRIBUTION OF PATIENTS WITH HCC WHO UNDERWENT MWA

A total of 34 patients diagnosed with HCC underwent MWA as the treatment of choice during the study period. The age ranged from 45 - 81 years with a mean age of 62.5 years. The age wise distribution of these patients is shown in Table 6 and Figure 3

Table 6: Age wise distribution of patients with HCC who underwent MWA

Age group (years)	No. of cases	Percentage
< 50	3	8.8%
51-60	11	32.4%
61-70	12	35.3%
> 70	8	23.5%
Total	34	100.0%

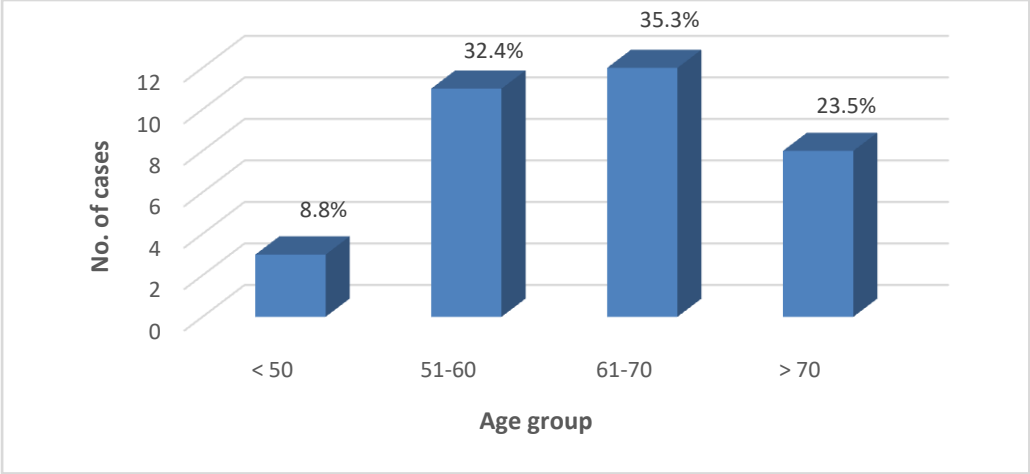


Figure 3- Age wise distribution of patients with HCC who underwent MWA

SEX WISE DISTRIBUTION OF PATIENTS WITH HCC WHO UNDERWENT MWA

Out of a total of 34 patients with HCC who underwent MWA, 28 were male and 6 were female, details of which are illustrated in Table 7 and Figure 4

Table 7: Sex wise distribution of HCC patients who underwent MWA

SEX	NO. OF CASES	PERCENTAGE
FEMALE	6	17.6%
MALE	28	82.4%
TOTAL	34	100.0%

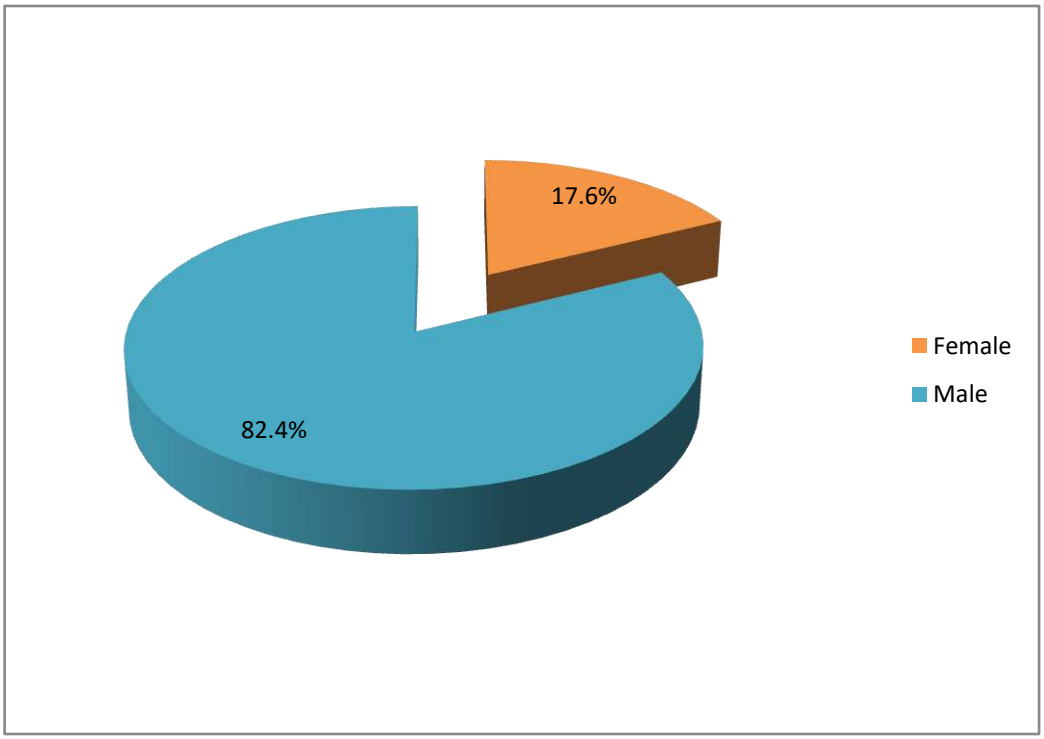


Figure 4: Sex wise distribution of HCC patients who underwent MWA

RISK FACTORS ASSOCIATED WITH CIRRHOSIS

The background of liver cirrhosis was found to be associated with the following risk factors: chronic alcohol use, HBV, HCV, combined risk of alcohol with HBV and HCV infection and NASH. The number and proportion of cases with the above-mentioned risk factors are elaborated in Table 8 and Figure 5

Table 8: Risk factor associated with cirrhosis

RISK FACTOR ASSOCIATED WITH CIRRHOSIS	NO. OF CASES	PERCENTAGE
ALCOHOL	13	38.2%
HBV	2	5.9%
HBV and ALCOHOL	1	2.9%
HCV	8	23.5%
HCV and ALCOHOL	2	5.9%
NASH	8	23.5%
Total	34	100.0%

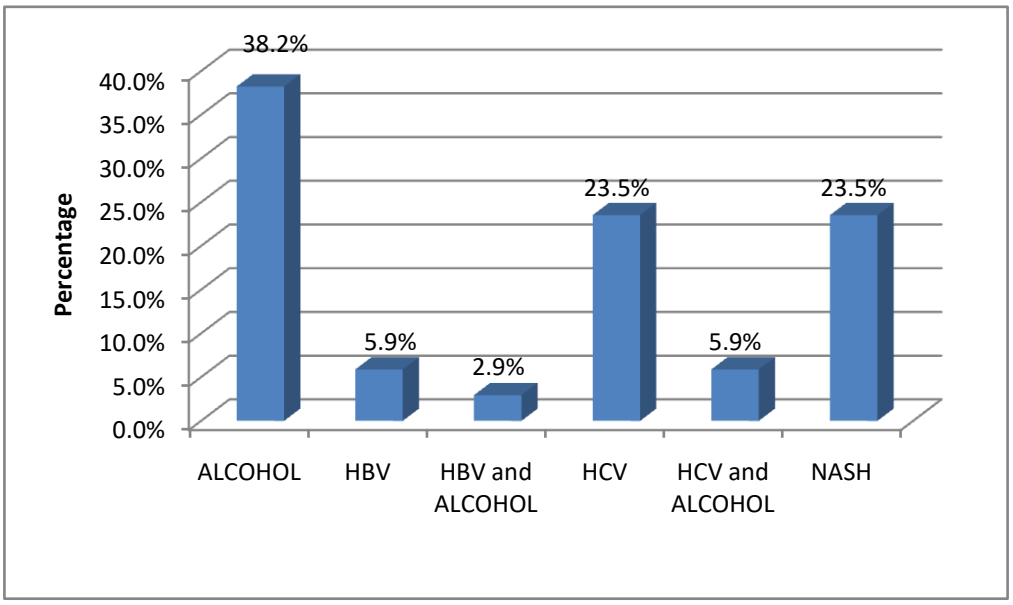


Figure 5: Risk factor associated with cirrhosis

Other lifestyle choices, such as smoking and opium use were also seen in few of the cases, along with chronic alcohol use. The number and proportion of cases are elaborated in Table 9 and Figure 6.

Table 9: Alcohol, smoking and opium users among the patients

	No. of cases	Percentage
ALCOHOL	9	26.5%
ALCOHOL+SMOKING	4	11.8%
ALCOHOL+SMOKING+OPIUM	3	8.8%

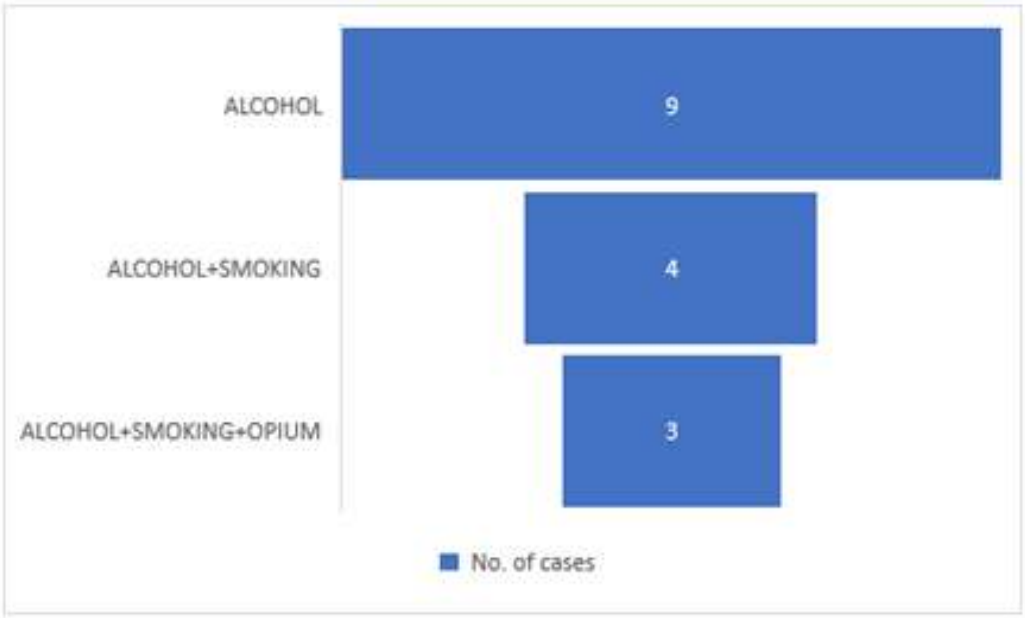


Figure 6: Alcohol, smoking and opium users among the patients

2) RESULTS OF THE CLINICAL DATA OF THE PATIENTS

The severity of CLD/ cirrhosis and liver function status of the patient was scored objectively using the Child-Pugh classification, based on total bilirubin, serum albumin, INR, presence of ascites or hepatic encephalopathy. The number of cases that were categorised as Child-Pugh class A and B are elaborated in Table 10 and Figure 7.

Table 10: Child-Pugh classification of the cases

CHILD-PUGH	NO. OF CASES	PERCENTAGE
CLASS A	21	61.8%
CLASS B	13	38.2%
Total	34	100.0%

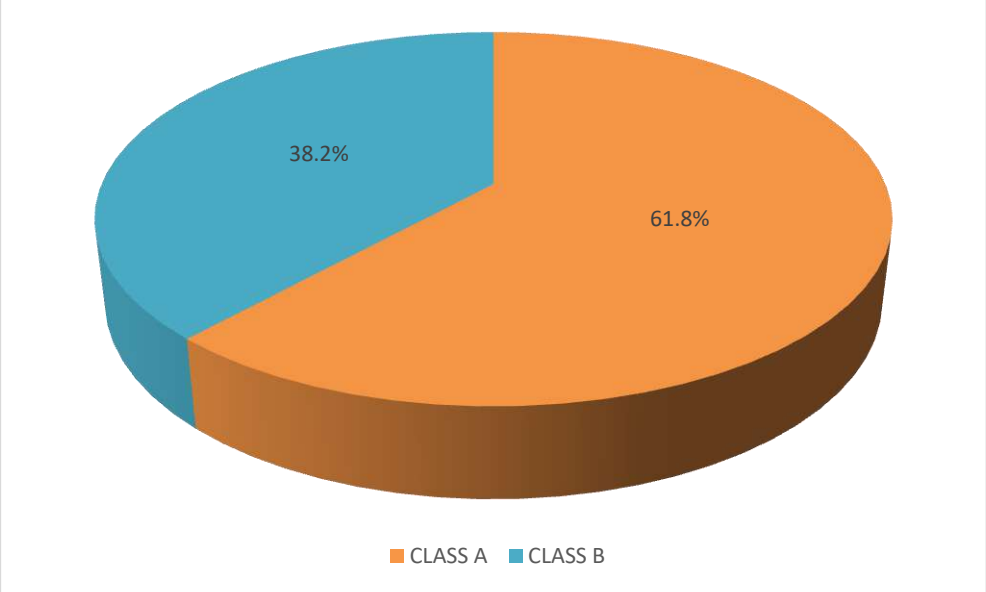


Figure 7: Child-Pugh classification of the cases

Model for End stage Liver Disease (MELD) scores of the patients were calculated using their serum bilirubin, creatinine and INR levels. The score ranged from 6 to 24. Table 11 and Figure 8.

Table 11: MELD scores of the patients

MELD	NO. OF CASES	PERCENTAGE
6	1	2.9%
7	5	14.7%
8	3	8.8%
9	6	17.6%
10	3	8.8%
11	3	8.8%
12	5	14.7%
13	2	5.9%
14	2	5.9%
15	1	2.9%
18	1	2.9%
20	1	2.9%
24	1	2.9%

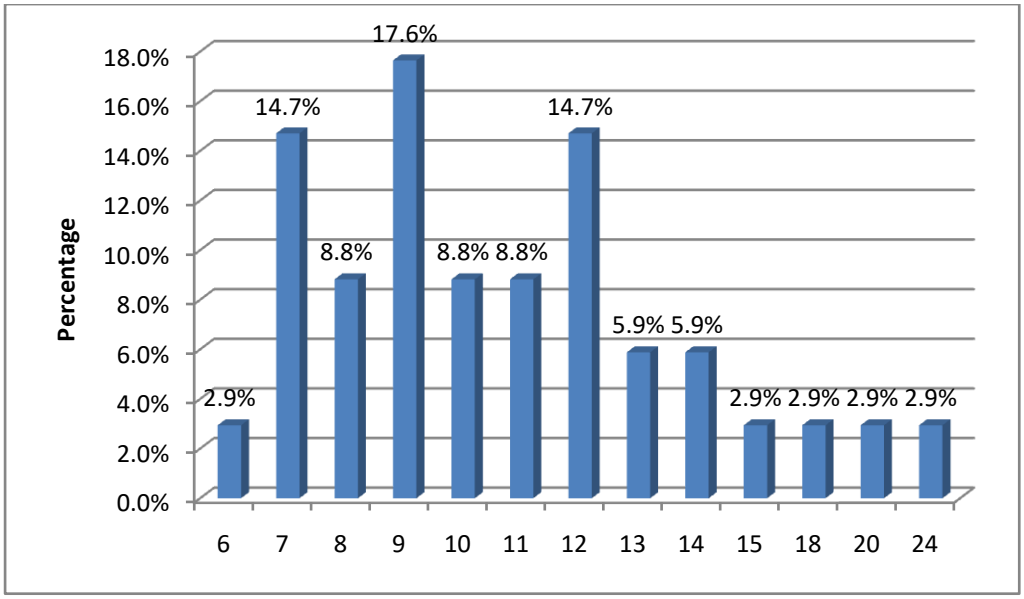


Figure 8: MELD scores of the patients

The BCLC stages of all the cases were calculated depending on the ECOG performance status, Child-Pugh score, and radiologic tumor extent (number of tumors, tumor size, vascular invasion, nodal and extrahepatic spread). The maximum number of cases were early stage A, followed by intermediate stage B and lastly Very early stage 0. Table 12, Figure 9.

Table 12: BCLC stages of the cases

BCLC STAGE	NO. OF CASES	PERCENTAGE
Very early Stage0	3	8.8%
Early Stage A	17	50.0%
Intermediate Stage B	14	41.2%

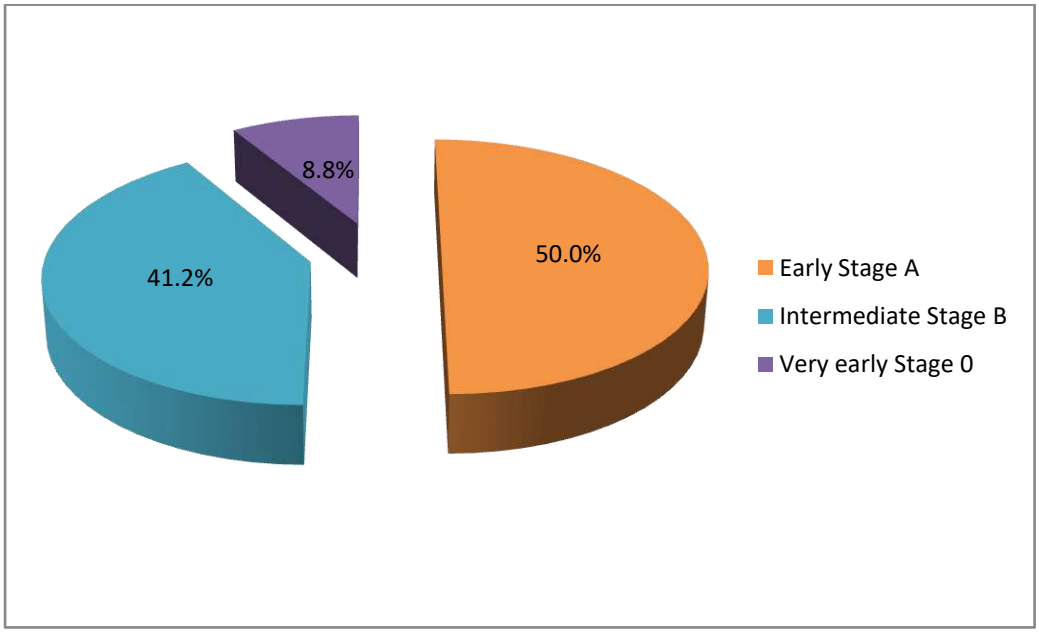


Figure 9: BCLC stages of the cases

3) RESULTS OF THE PRE-ABLATION IMAGING FINDINGS

Each of the 34 patients included in the study had either one, two or a maximum of three lesions each. Most of the patients had one lesion and few had three lesions. The details are tabulated and illustrated in Table 13 and Figure 10 respectively.

Table 13: Number of lesions per patient

NO. OF LESIONS	NO. OF CASES	PERCENTAGE
1	26	76.5%
2	5	14.7%
3	3	8.8%

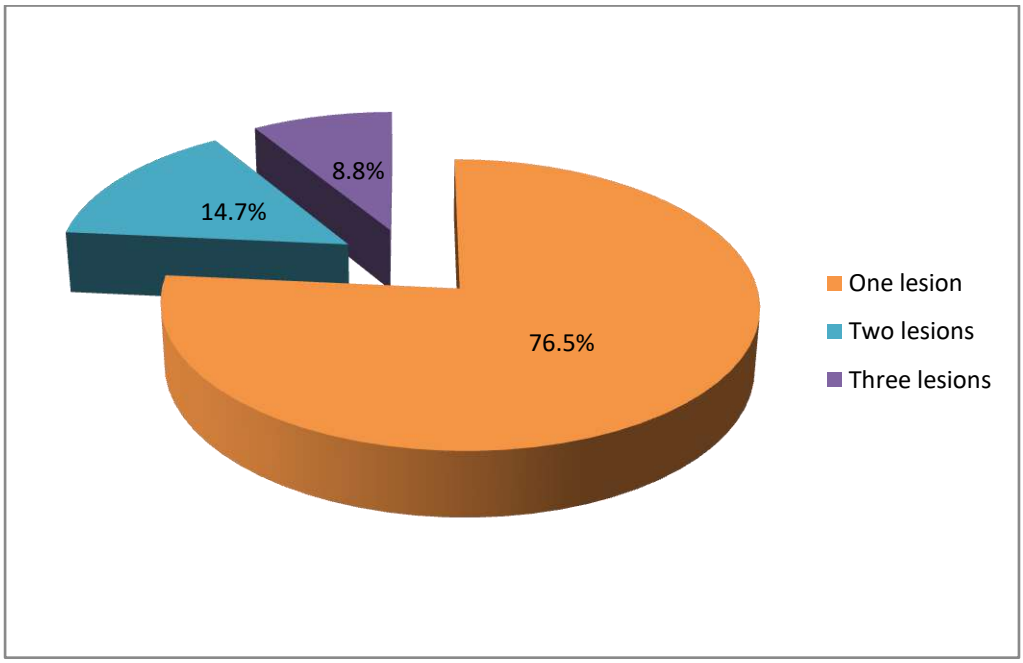


Figure 10: Number of lesions per patient

The Couinaud segments involved by the lesions were identified on the baseline CT/MRI and are tabulated and illustrated in the Table 14 and Figure 11 respectively.

Table 14: Segmental distribution of the lesions identified on imaging

COUINAUD SEGMENT	NO. OF CASES	PERCENTAGE
I	2	4.5%
II	2	4.5%
II/III	1	2.3%
III	1	2.3%
IV	6	13.6%
V	4	9.1%
V/VI	1	2.3%
VI	13	29.5%
VI/VII	1	2.3%
VII	5	11.4%
VIII	8	18.2%
Total	44	100.0%

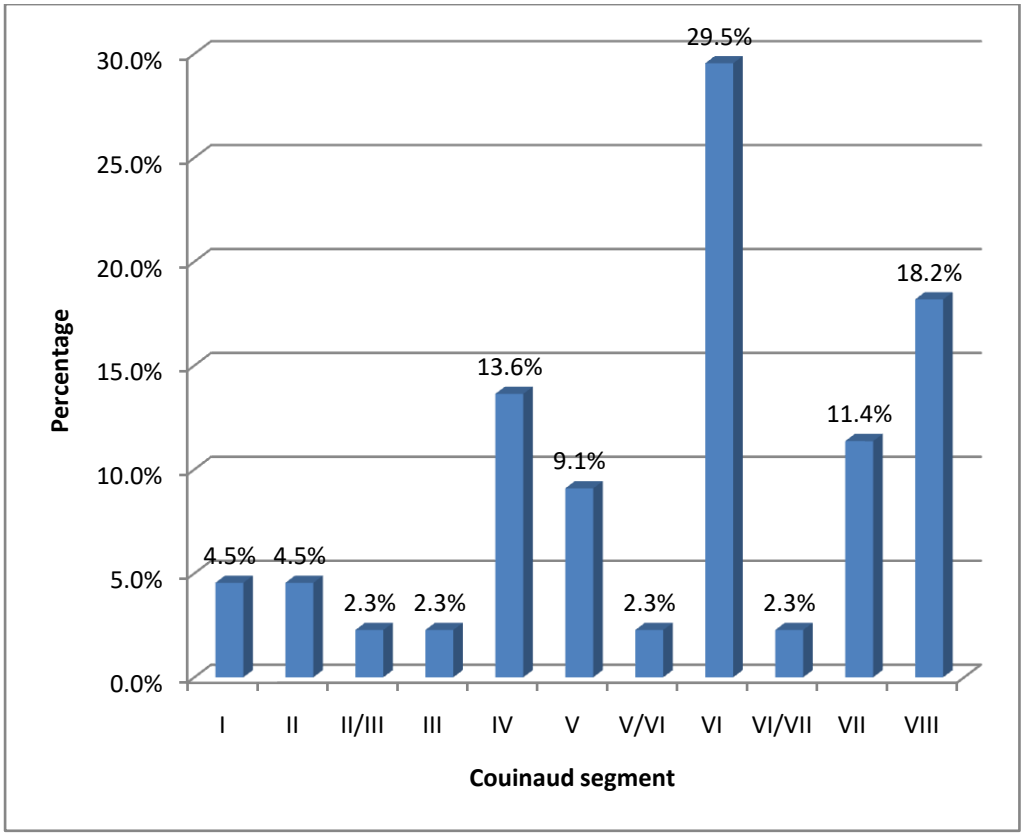


Figure 11: Segmental distribution of the lesions identified on imaging

The total number of HCC lesions ablated were 44, which ranged from size 0.8 to 5.0 cm, as shown in Table 15 and Figure 12. Out of these, the lesions that were >3.0cm and ≤5.0cm, which are beyond the BCLC guidelines for ablation are separately tabulated and illustrated in Table 16 and Figure 13.

Table 15: Number of lesions as per the size

SIZE OF LESION (cm)	NO. OF LESIONS	PERCENTAGE
0.1 - 1.0	2	4.5%
1.1 - 2.0	15	34.1%
2.1 - 3.0	12	27.3%
3.1 - 4.0	10	22.7%
4.1 - 5.0	5	11.4%

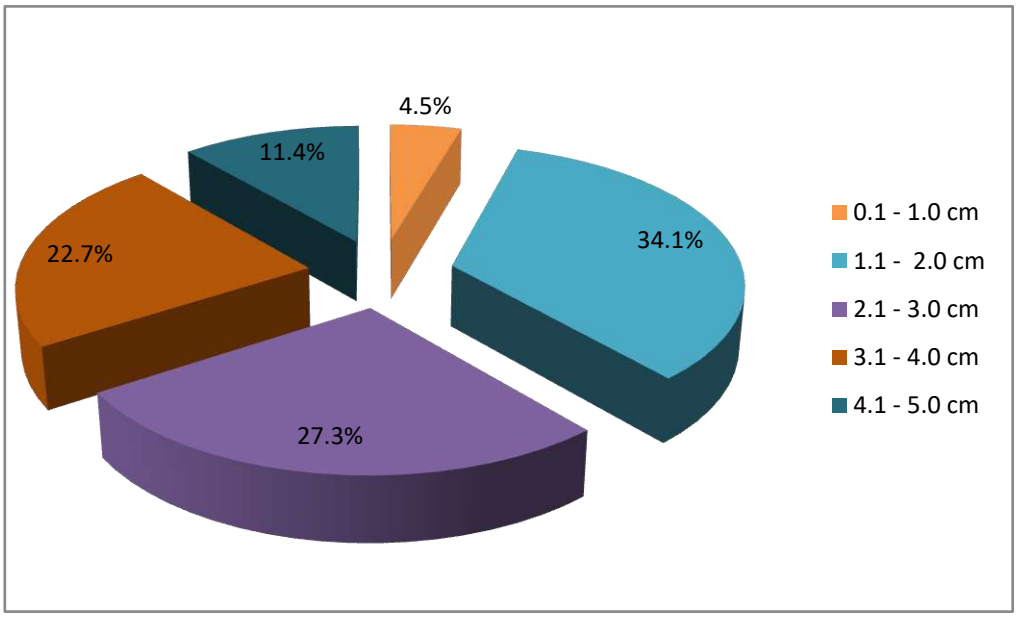


Figure 12: Number of lesions as per the size

Table 16: Number of lesions beyond 3.0cm and less than 5.0cm

SIZE OF LESION (cm)	NO. OF LESIONS	PERCENTAGE
0-3.0	29	65.9%
3.1-5	15	34.1%
Total	44	100.0%

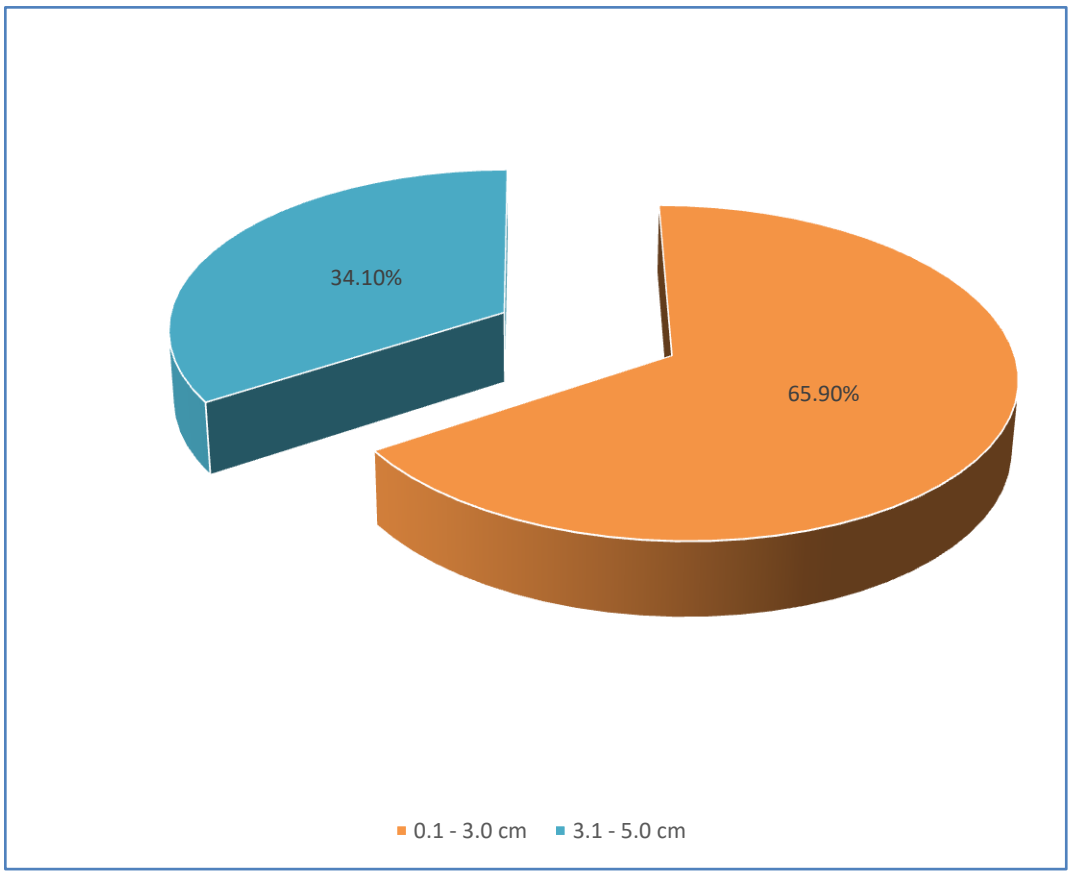


Figure 13: Number of lesions beyond 3.0cm and less than 5.0cm

All the lesions ablated were diagnosed as either LI-RADS 5(definitely HCC) or LI-RADS 4 (probably HCC), in the CT/MRI triphasic imaging done prior to the ablation as shown in Table 17 and Figure 14

Table 17: LI-RADS diagnosis of the lesions

LI-RADS (LR)	NO. OF CASES	PERCENTAGE
LI-RADS - 4	3	6.8%
LI-RADS - 5	41	93.2%
Total	44	100.0%

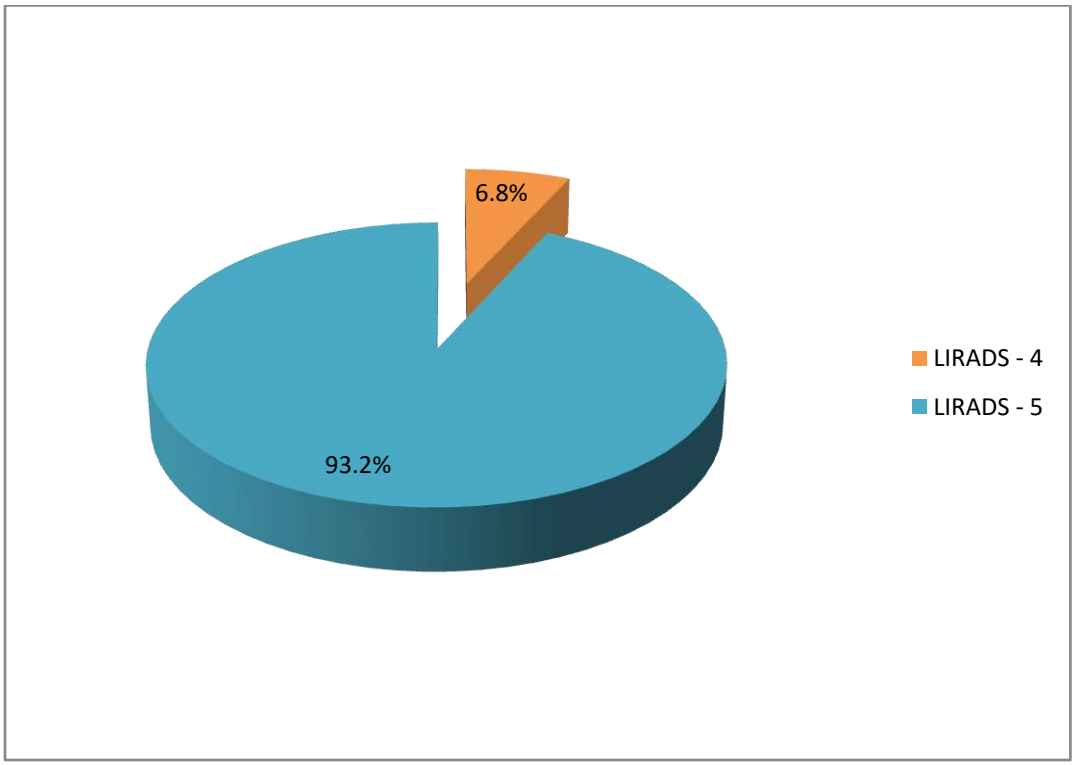


Figure 14: LI-RADS diagnosis of the lesions

4) RESULTS OF THE MWA PROTOCOL

A set 'burn' protocol was used to ablate each lesion, with a fixed ablation zone and time. The time used for ablating each lesion is shown in Table 18 and Figure 15. An average of the MWA protocol used, including the maximum and minimum ablation dimensions and time, for each lesion according to its size, is shown in Table 19 and Figure 16

Table 18: Time taken to ablate each lesion

MWA TIME (min)	NO. OF LESIONS	PERCENTAGE
1	5	11.4%
2	11	25.0%
3	6	13.6%
5	8	18.2%
10	2	4.5%
13	7	15.9%
15	5	11.4%

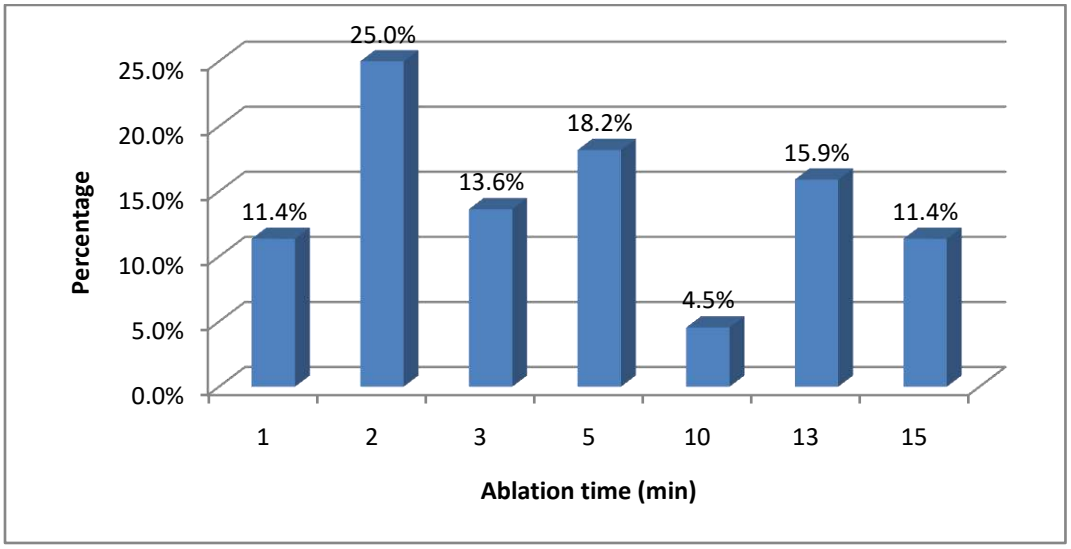


Figure 15: Time taken to ablate each lesion

Table 19: Average MWA protocol used for the average size of lesion.

	N	Minimum (cm)	Maximum(cm)	Mean (cm)	Std. Deviation
SIZE OF LESION(cm)	44	0.8	5.0	2.6	1.2
MWA ZONE (cm)	44	2.8	5.5	3.9	0.8
MWA TIME (min)	44	1.0	15.0	6.2	5.2
POWER (WATTS)	44	100.0	100.0	100.0	

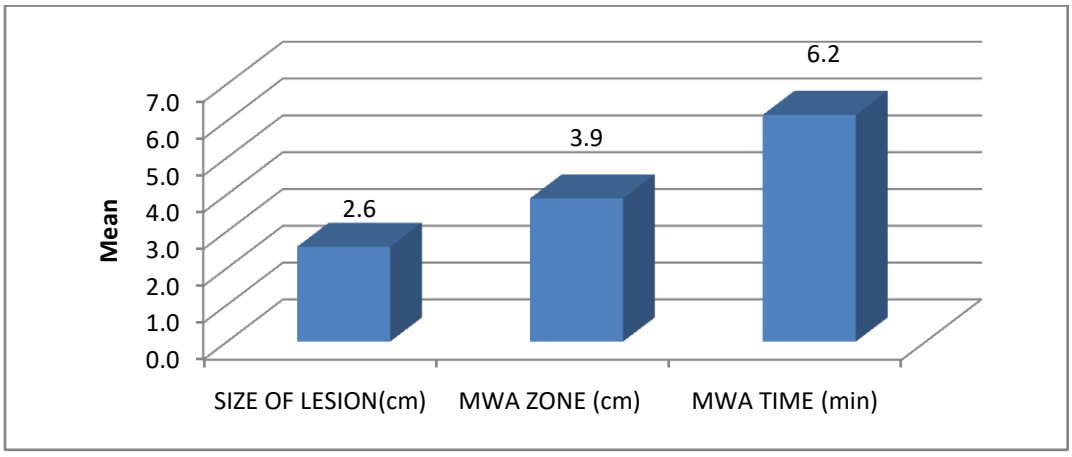


Figure 16: Average MWA protocol used for the average size of lesion.

For each set of lesions according to their size, the corresponding MWA zone applied is compared in Table 20 and Figure 17.

Table 20: Ablation zone applied for each set of lesions according to their size

		MWA ZONE (cm)		Total
		1.1-3	3.1-5	
SIZE OF LESION (cm)	0-1.0	2	0	2
	1.1-3	3	24	27
	3.1-5	0	15	15
Total		5	39	44

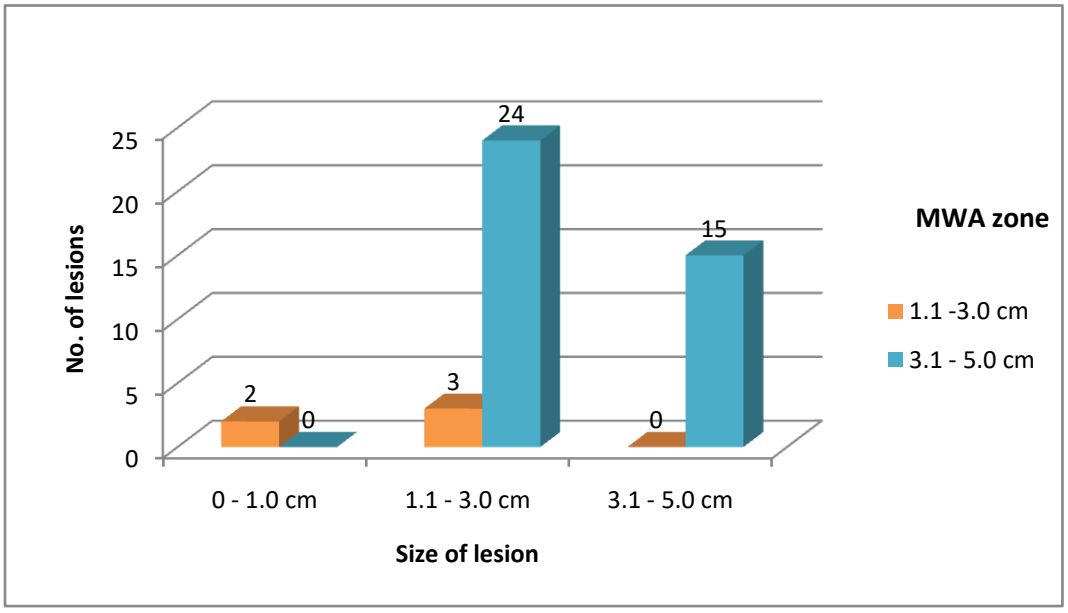


Figure 17: Ablation zone applied for each set of lesions according to their size

The mean size of lesions were compared with the mean MWA zone. A p-value of 0.001 was calculated which shows significant increase in ablation zone compared to the size of the lesion, the results of which are depicted in Table 21 and Figure 18.

Table 21: Mean size of lesion compared to mean MWA zone

	Mean	Std. Deviation	Std. Error Mean	t	p-value	Mean Difference	SD difference
Lesion size(cm)	2.58	1.176	.177	-15.978	0.001	-1.31	0.544
MWA zone(cm)	3.89	.761	.115				

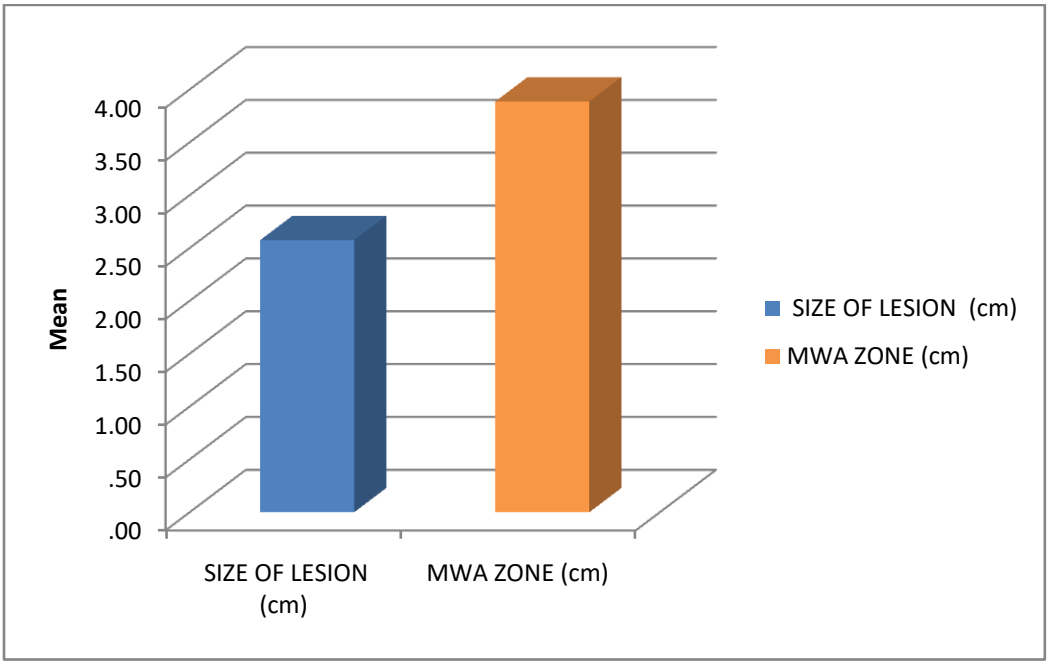


Figure 18: Mean size of lesion compared to mean MWA zone

Spearman's correlation coefficient was calculated to compare the strength of association between the size of lesions to that of the ablation zone applied. A correlation coefficient of 0.906 was found, suggesting a strong positive correlation between the two, implying that the MWA size was adequately widened as the size of the lesion increased. This is illustrated in Table 22 and Figure 19.

Table 22: Spearman's rho comparing the size of the lesion and the MWA zone applied

Spearman's rho		**MWA ZONE (cm)**
SIZE OF LESION (cm)	Correlation Coefficient	0.906
	p-value	0.001
	N	44

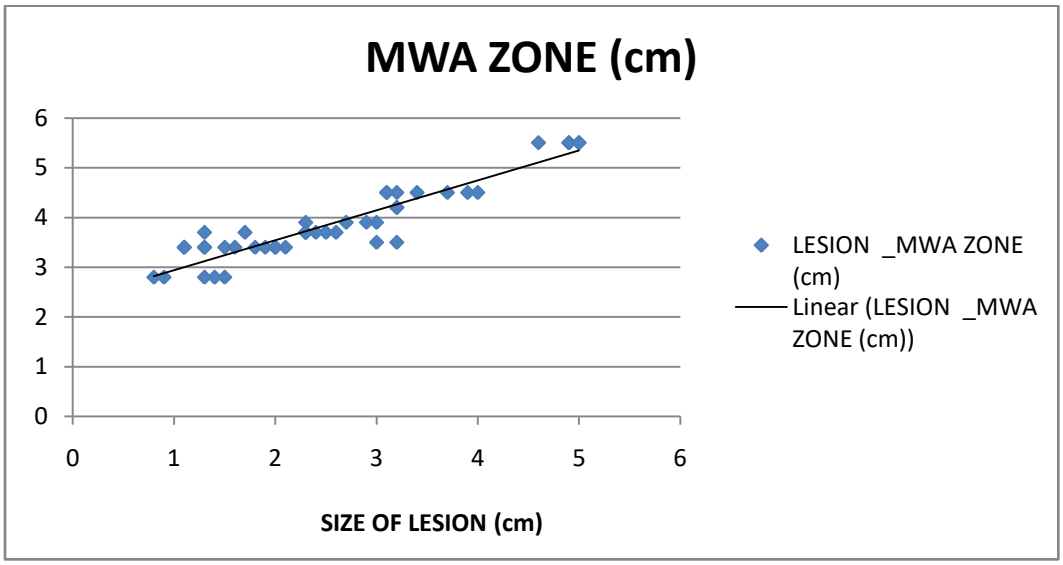


Figure 19: Spearman's rho comparing the size of the lesion and the MWA zone applied

5) FOLLOW UP AT 6 WEEKS

At 6 weeks follow up, 3 of the patients were deceased. The imaging findings of the remaining 31 patients were compared to their pre-ablation imaging. A total of 40 lesions were compared with their LI-RADS treatment response (LT-TR) as shown in Table 23 and Figure 20.

Table 23: LI-RADS Treatment Response of the lesions at 6 weeks follow up

LI-RADS TREATMENT RESPONSE (LR-TR) AT 6 WEEKS	NO. OF LESIONS	PERCENTAGE
LR-TR EQUIVOCAL	1	2.5%
LR-TR NON VIABLE	36	90.0%
LR-TR VIABLE	3	7.5%
Total	40	100.0%

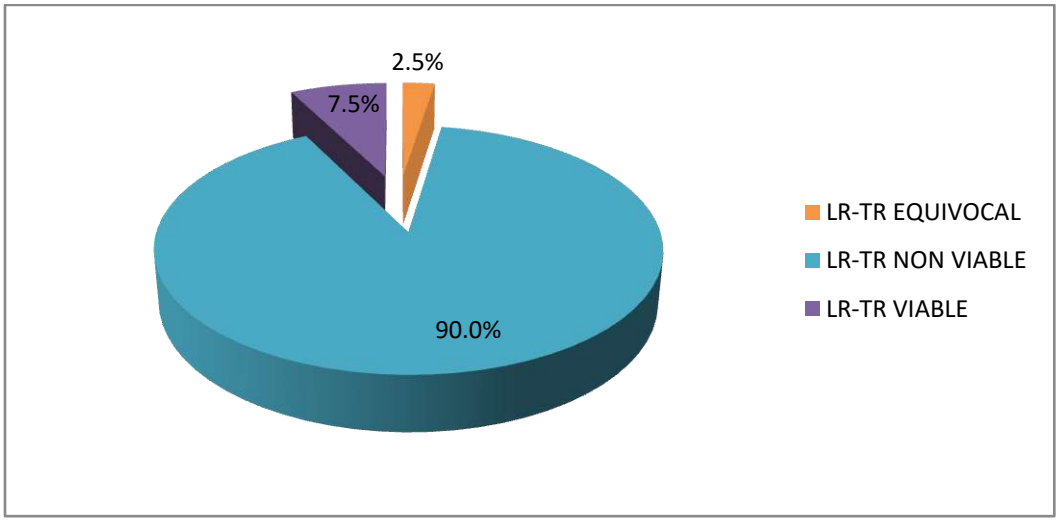


Figure 20: LI-RADS Treatment Response of the lesions at 6 weeks follow up

Additionally, the response to ablation at 6 weeks follow up, in lesions beyond the BCLC guidelines, i.e lesions sized ≥ 3.0 cm, were also analysed. A p-value of 0.343 was obtained, implying no statistically significant difference between the lesions <3.0cm and those ≥ 3.0 cm. the results are shown in Table 24 and Figure 21.

Table 24: LI-RADS Treatment response at 6 weeks of lesions ≥ 3.0 cm (beyond the BCLC guidelines)

		LI-RADS TREATMENT RESPONSE (LR-TR) AT 6 WEEKS			Total	Chi-square value	p-value
		LR-TR EQUIVOCAL	LR-TR NON VIABLE	LR-TR VIABLE			
SIZE OF LESION (cm)	≤ 3	1	23	3	27	2.14	0.343
	3.1-5	0	13	0	13		
Total		1	36	3	40		

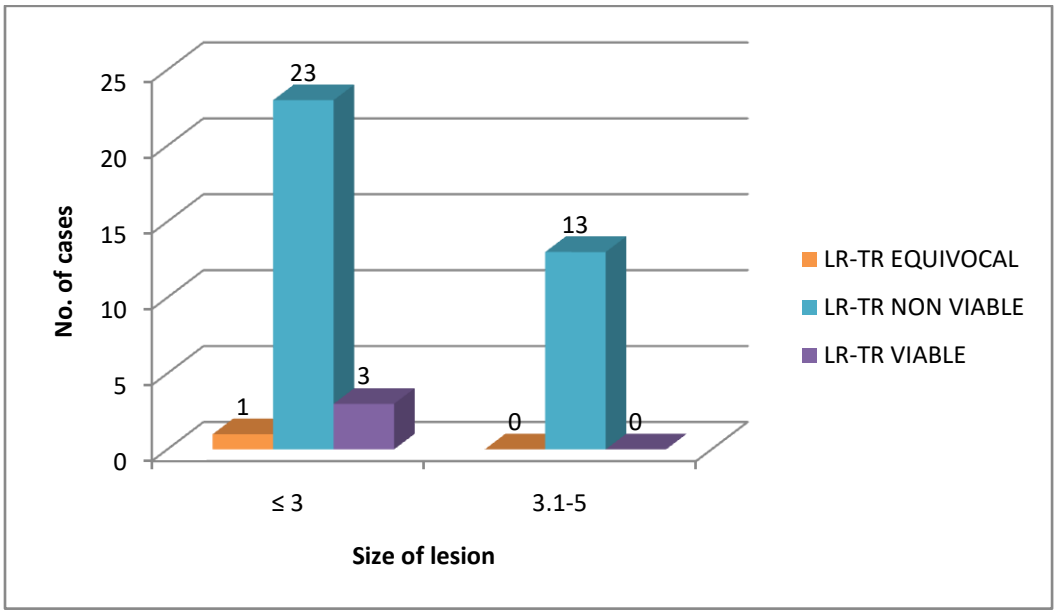


Figure 21: LI-RADS Treatment response at 6 weeks of lesions ≥ 3.0 cm (beyond the BCLC guidelines)

The overall patients' response to MWA at 6 weeks was analysed by mRECIST, as shown in Table 25 and Figure 22.

Table: 25: Overall patients' response to MWA at 6 weeks follow up by mRECIST

mRECIST at 6weeks	No. of cases	Percentage
CR	24	77.4%
PD	6	19.4%
SD	1	3.2%
Total	31	100.0%

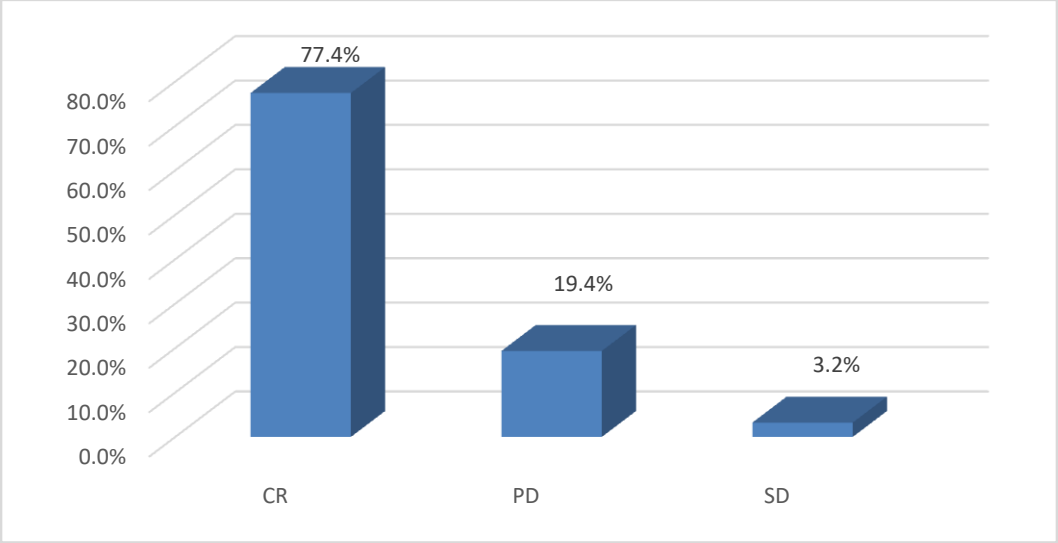


Figure 22: Overall patients' response to MWA at 6 weeks follow up by mRECIST

A comparison of the overall treatment response to MWA depending on the number of lesions per patient is shown in Table 26 and Figure 23. A p value of 0.046 is calculated implyingstatistically significant correlation between the number of lesions ablated per patient to the overall mRECIST at 6 weeks follow up.

Table 26: mRECIST at 6weeks compared to the number of lesions per patient

		NO.OF LESIONS						Total	Chi-square value	p-value
		1	1	2	2	3	3			
mRECIST at 6weeks	**CR**	20	80.0%	2	66.7%	2	66.7%	24	10.333	0.035
	PD	5	20.0%	1	33.3%	0	0.0%	6		
	SD	0	0.0%	0	0.0%	1	33.3%	1		
Total		25	100.0%	3	100.0%	3	100.0%	31		

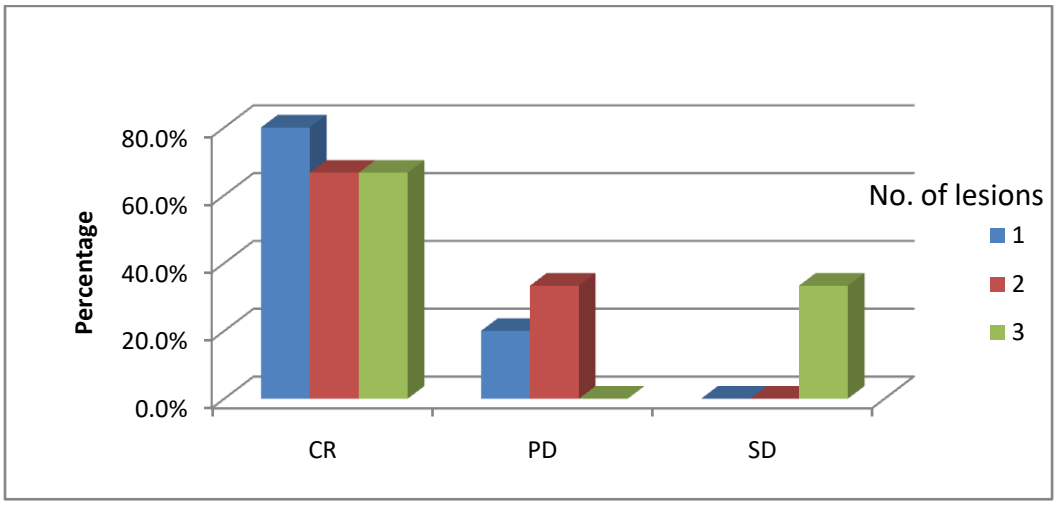


Figure 23: mRECIST at 6weeks compared to the number of lesions per patient

6) FOLLOW UP AT 3 MONTHS

At 3 months follow up, 31 patients were compared to their pre-ablation imaging. A total of 40 lesions were compared with their LI-RADS treatment response (LT-TR) is shown in Table 27 and Figure 24.

Table 27: LI-RADS Treatment Response of the lesions at 3 months follow up

LI-RADS TREATMENT RESPONSE (LR-TR) AT 3 MONTHS	NO. OF LESIONS	PERCENTAGE
LR-TR NON VIABLE	35	87.5%
LR-TR VIABLE	5	12.5%
Total	40	100.0%

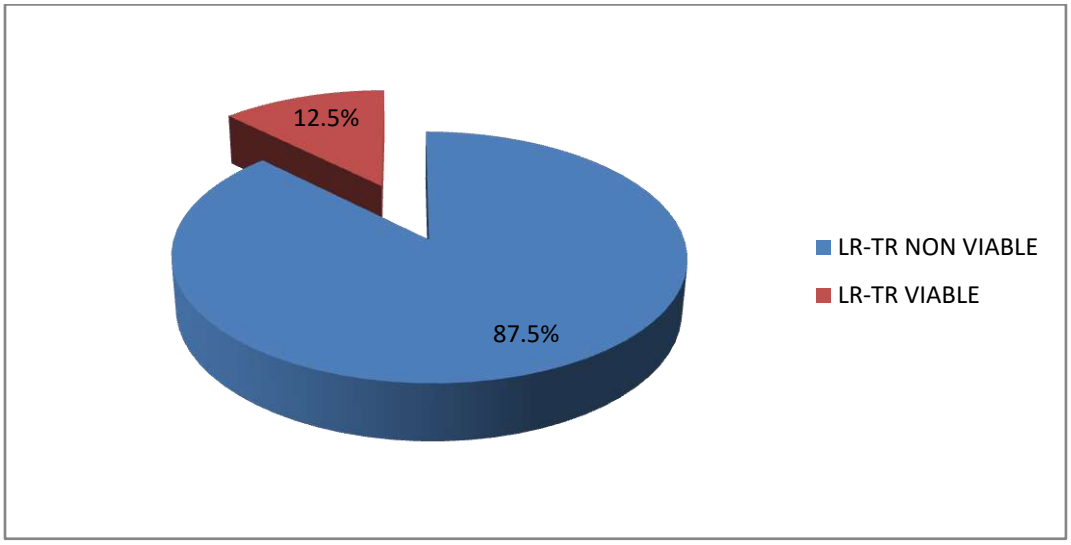


Figure 24: LI-RADS Treatment Response of the lesions at 3 months follow up

Moreover, the response to ablation at 3 months follow up, in lesions <3.0cm and those sized ≥ 3.0 cm, were also analysed. A p-value of 0.097 was obtained, implying no statistically significant difference between the two groups. The results are shown in Table 28 and Figure 25.

Table 28: LI-RADS Treatment response at 3 months of lesions ≥ 3.0 cm (beyond the BCLC guidelines)

		LI-RADS TREATMENT RESPONSE (LR-TR) AT 3 MONTHS		**Total**	**Chi-square value**	**p-value**
		LR-TR NON VIABLE	**LR-TR VIABLE**			
SIZE OF LESION (cm)	≤ 3	22	5	27	2.751	0.097
	3.1-5	13	0	13		
Total		35	5	40		

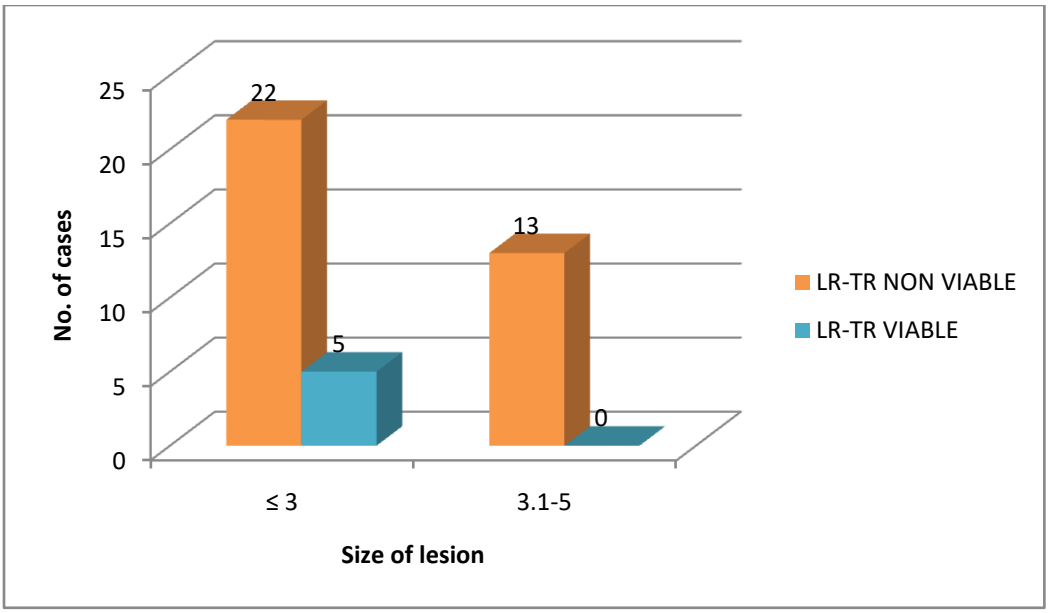


Figure 25: LI-RADS Treatment response at 3 months of lesions ≥ 3.0 cm (beyond the BCLC guidelines)

The overall patients' response to MWA at 3 months by mRECIST, is shown in Table 29 and Figure 26.

Table: 29: Overall patients' response to MWA at 3 months follow up by mRECIST

mRECIST AT 3 MONTHS	NO. OF CASES	PERCENTAGE
CR	19	61.3%
PD	11	35.5%
SD	1	3.2%
Total	31	100.0%

Figure 26: Overall patients' response to MWA at 3 months follow up by mRECIST

A comparison of the overall treatment response to MWA at 3 months depending on the number of lesions per patient is shown in Table 30 and Figure 27. A p value of 0.041 is calculated implying statistically significant correlation between the number of lesions ablated per patient to the overall mRECIST at 3 months follow up.

Table 30: mRECIST at 3 months compared to the number of lesions per patient

		NO.OF LESIONS						Total	Chi-square value	p-value
		1		2		3				
		No. of cases	Percentage	No. of cases	Percentage	No. of cases	Percentage			
mRECIST at 3 months	CR	15	60.0%	2	66.7%	2	66.7%	19	13.154	0.041
	PD	10	40.0%	1	33.3%	0	0.0%	11		
	SD	0	0.0%	0	0.0%	1	33.3%	1		
Total		25	100.0%	3	100.0%	3	100.0%	31		

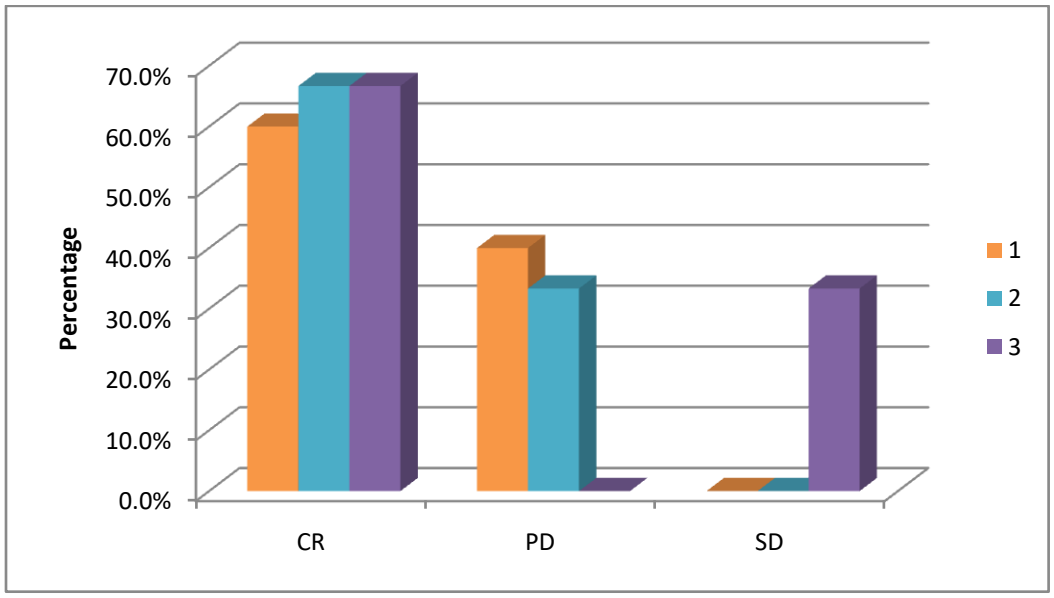


Figure 27: mRECIST at 3 months compared to the number of lesions per patient

The patients in whom mRECIST evaluation did showed progressive disease, the causes were evaluated. These are shown in Table 31 and Figure 28

Table 31: Progressive disease on mRECIST at follow ups

	NO. OF CASES	PERCENTAGE
One new lesion at 6 weeks	3	8.8%
One new lesion at 3 months	5	14.7%
More than one new lesion at 6 weeks	3	8.8%
More than one new lesion at 3 months in those who had PD at 6 weeks	2	5.9%

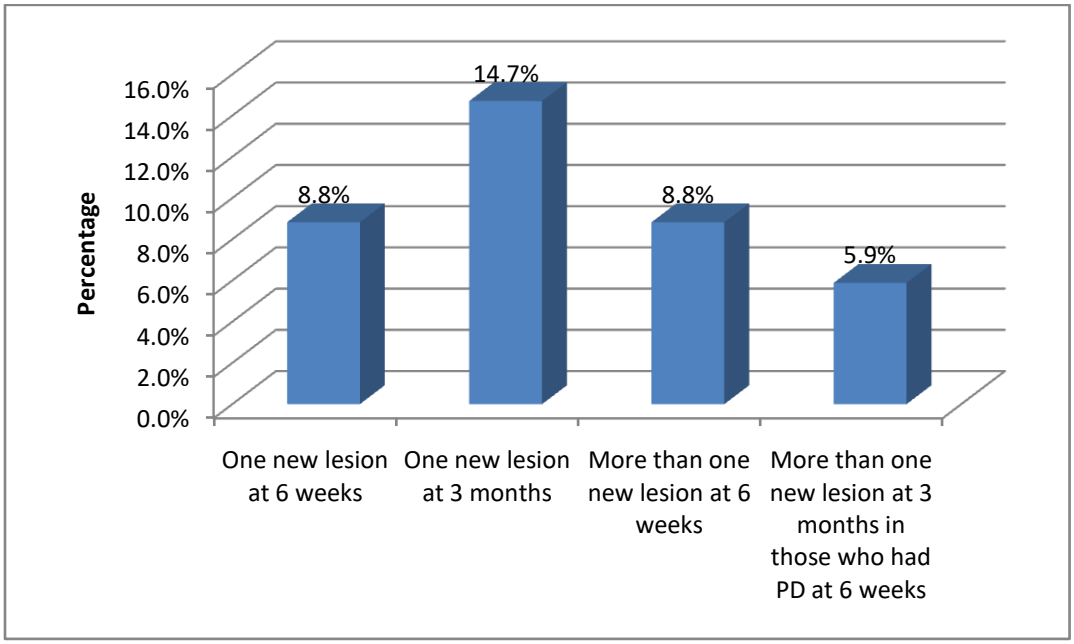


Figure 28: Progressive disease on mRECIST at follow ups

The outcome of the 34 patients in terms of survival or death is depicted in Table 32 and Figure 29.

Table 32: Outcome of the patients in terms of survival or death

OUTCOME	NO. OF CASES	PERCENTAGE
Survival	31	91.2%
Death	3	8.8%
Total	34	100.0%

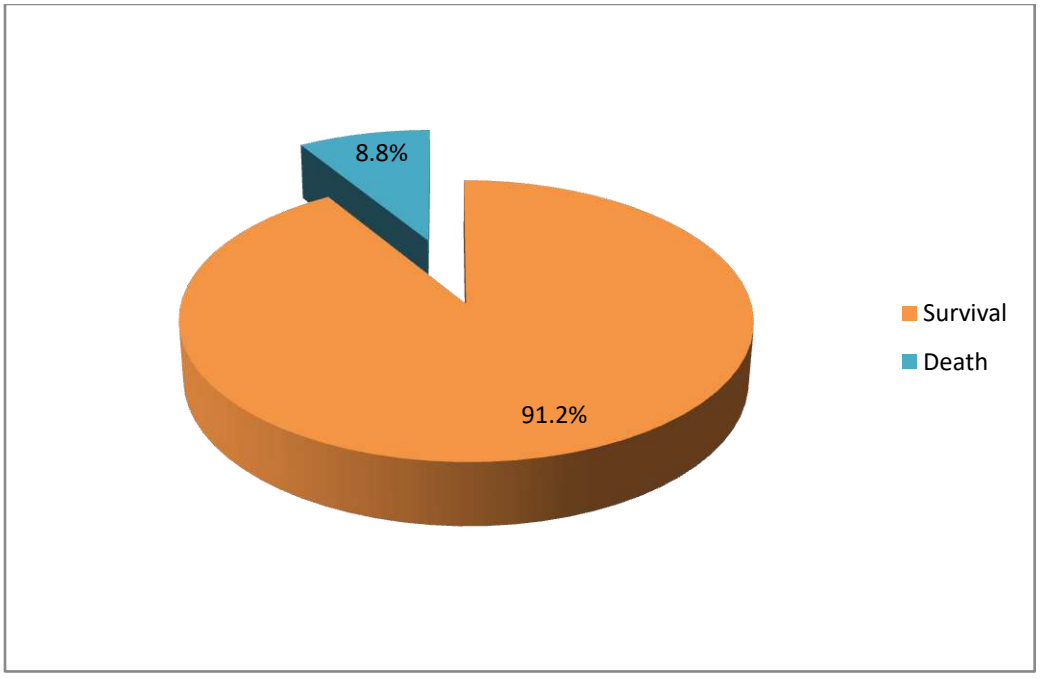


Figure 29: Outcome of the patients in terms of survival or death

DISCUSSION

This study was conducted on 34 patients who were diagnosed with HCC on the basis of their CT/MRI triphasic imaging in the department of Radiodiagnosis in Dayanand Medical College and Hospital, Ludhiana, from February 2021 to June 2022 and who after thorough discussion with their primary clinician and intervention radiologist underwent ultrasound guided MWA as the treatment of choice for HCC. The patients were followed up at 6weeks and 3 months post the ablation and their imaging findings were compared.

Age of the patients with HCC in this study, ranged from 45 to 81 years, with a mean age of 62.5 years. The highest incidence of HCC was in the age group of 61-70 years (35.3%) followed by 51-60 years (32.4%). 82.4% of the patients in the study were male and 17.6% were female.

In our study all the patients with HCC had a background of CLD/Cirrhosis. Alcohol was the most common risk factor among them with as high as 47.1% of the cases being chronic alcoholics. 2.9% of the cases having both alcohol and HBV as the risk factors, and 5.9% having both alcohol and HCV associated risks. In addition to being chronic alcohol users, 11.8% of the cases were smokers and 8.8% of them were smokers and opium users. 23.5% of the cases were HCV reactive, while 5.9% were HBV reactive. Furthermore, a risk association was also found in patients with NASH, accounting for 23.5% of the cases. A study by Aileen Baecker et al.reported HBV as the highest risk factor for HCC worldwide (44% of the cases) with majority in Asia and attributed 21% of the cases to HCV.[41] In a study by Akinyemiju et al. risk of HCC associated with HCV was reported to be highest in North America, Europe and Japan. They reported 33%, 30% and 21% of liver cancer deaths associated with HBV, alcohol and HCV respectively.[42] A study by Jin-Young Choy et al. similar to our study, reported the heavy use of alcohol and smoking to be high risk factors associated with cirrhosis.[2]

The liver function status of the cases included in the study were either Child-Pugh class A (61.8%) or Child-Pugh class B (38.2%), based on their total bilirubin, serum albumin, INR, presence or absence of ascites and hepatic encephalopathy. This is in keeping with the BCLC guidelines, which recommends ablation therapy for HCC patients with a preserved liver function status.[8]

A study by Conticchio M. et al. reported a Model for End-stage Liver Disease (MELD) score of >10 to be an independent risk factor for overall survival and a poor prognostic factor for tumor recurrence post ablation.[43] In our study, the MELD scores ranged from 6 to 24 with a score of 9 being the most common (17.6%), implying a predicted 3 months mortality rate of 1.9% for these patients. 52.3% of the cases in our study had a MELD score of ≤10.

IMAGING FINDINGS

A baseline CT/MRI triphasic was done in 34 patients, with a total of 44 lesions; 93.2% of which were LI-RADS V (definitely HCC) and 6.8% of which were LI-RADS IV (probably HCC) lesions. None of the patients in this study underwent any fine needle aspiration cytology or biopsy for histopathological proof of HCC, prior to the ablation.

In our study 72.7% of the lesions were identified in the right lobe of liver and 22.7% in the left. 4.2% of the lesions were in the caudate lobe (segment I). The most commonly involved Couinaud segment was segment VI (29.5%). A study by Matteo Renzulli et al. which evaluated the segmental distribution of 322 HCC nodules in 217 cirrhotic patients, identified 72.7% of the lesions in the right lobe of liver, 24.5% in the left and 2.8% in the caudate lobe, with segment VIII being the most common location.[44]

ASSESSMENT OF MWA PROTOCOL

A set ‘burn protocol’ was applied on each lesion with a fixed time of ablation ranging from one minute to 15 minutes, using a power of 100W on each lesion. The most commonly used ablation time was 2 minutes in 25% of the lesions. Most of the ablation zones were in the range of 3.1 – 5.0 cm (88.6%), applied according to each lesion’s size.

In this study the average size of the HCC lesions were 2.6 cm +/- 1.2 SD, with a mean ablation zone of 3.9 cm +/- 0.8. The average ablation margin was 1.31 cm +/- 0.5 SD. A strong positive Spearman’s correlation coefficient of 0.906 was found between the size of lesion and the MWA zone, implying that the ablation margins were increased adequately as per the size of the lesion. This is in keeping with the minimum ablation margin of 5mm for adequate ablation, recommended in MWA of HCC in a study by Ljin Joo et al.[45]

ASSESSMENT OF TREATMENT RESPONSE AT FOLLOW UP

At 6 weeks follow up, 3 patients were found to be deceased. The cause of death in one of them was reported as decompensated cirrhosis. This patient, was categorized as Child-Pugh class B, and BCLC stage B, with a history of chronic alcohol consumption. The second case was reported to have succumbed to a bleed in the post-ablation cavity reported as a large hematoma on ultrasound at 4 days post-ablation. This patient was a chronic alcohol abuser and was HCV positive, categorised as Child-Pugh class B and BCLC stage B, with a lesion sized 5cm. The cause of death in the third case was not documented as the patient was not hospitalized, but a verbal description by the relatives of hepatic encephalopathy like symptoms such as increased somnolence, gross confusion and disorientation were described, which could suggest decompensated cirrhosis as the probable cause of death. This patient was HCV positive, under Child-Pugh class A and BCLC stage A.

A study by Kong WT et al. explored major complications after ablation of hepatic tumors in 255 patients. The most serious complication was reported to be liver failure which had the highest fatality rate of 4.3% with worsening liver decompensation. Other major complications involved hydrothorax, tumor seeding, gastrointestinal bleeding, hyperglycemia, hepatic abscess and cardiac arrest.[46]

The imaging findings in the rest of the 31 patients (40 lesions in total) were compared to their baseline imaging at 6 weeks follow up. 90% of the lesions were LR-TR non-viable, 7.5% were LR-TR viable and 2.5% were LT-TR equivocal. The overall patient's response at 6 weeks in terms of mRECIST was: complete response in 77.4%, progressive disease in 19.4%, stable disease in 3.2%. At 3 months follow up, 87.5% and 12.5% of the lesions were LR-TR non-viable and LR-TR viable respectively, with mRECIST complete response in 61.3%, progressive disease in 35.5% and stable disease in 3.2%. Comparatively, in a study by Wei H et al. 19 patients with a total of 22 lesions were followed up until the day of death or until day of last follow up. 45.4% showed partial response, 31.8% complete response, 13.6% stable disease and 9% showed progressive disease.[29]

Our study revealed an overall survival of 91.2% at 6 weeks and 3 months, while Wei H et al. had an overall survival of 94.4%, 94.4% and 85.7% at 6 months, 1 year and 2 years follow up respectively.[29]

ANALYSIS OF PROGRESSIVE DISEASE

8.8% of the cases in our study were found to have one new lesion at 6 weeks and another 8.8% of the cases had more than one new lesion. 14.7% had one new lesion at 3 months. 25% of those had a new lesion at 6 weeks had a further disease progression with multiple new lesions detected at 3 months follow up. A retrospective study by Kit-Fai Lee et al. compared long-term outcomes in patients treated with MWA and RFA,

with an overall recurrence rate of 80.8% and 83% respectively. Local recurrence rate was 23.1% and 25.5% in MWA and RFA respectively.[47]

A study by W Liu et al. prospectively analysed response to ablation in HCC in 616 patients. In patients with a solitary lesion ≤ 3.0 cm, 83% exhibited relapse in short-interval (<4 months) surveillance group and 72% exhibited relapse in the long-interval (4-6 months) surveillance group. In those with multiple tumors ≤3 cm or solitary tumor between 3 and 5 cm, 77.2% and 18% showed relapse in short- and long- interval surveillance groups.[48]

ASSESSMENT OF RESPONSE TO MWA BASED ON SIZE OF THE LESION

As it has already been established, MWA is the recommended treatment for HCC in very early (0) and early BCLC stage (A), for a single lesion <2cm in size or 2-3 lesions, each with a maximum size of 3cm. In this study, MWA has been used for treating lesions within the BCLC treatment guidelines and also treating those measuring 3.0- 5cm in size, beyond the recommended BCLC guidelines. 76.5% of the patients included in this study had one lesion, while 14.7% and 8.8% of them had two and three lesions each respectively. Out of a total of 44 lesions, 34.1% were in the range of 3.1-5.0 cm which were categorised as intermediate BCLC stage B among other cases. At 6 weeks follow up, 40 lesions were assessed, having excluded 4 lesions of the 3 reported deaths. 85.1% of the lesions sized ≤3.0cm, were found to be LR-TR non-viable, and 100% of the lesions sized 3.0-5.0cm (beyond the BCLC guidelines) were found to be LR-TR non-viable. At 3 months follow up, 81.4% of the lesions ≤3.0cm and 100% of the lesions between 3.1-5.0cm were LR-TR non-viable. This implies that there was no statistically significant difference in treatment response to MWA in these two groups, with p-value of 0.343 and 0.097at 6 weeks and 3 months follow up respectively. From this analysis, it can be

drawn that that a good treatment response to MWA was achieved in patients staged as intermediate stage (B) BCLC in this study group.

A study by Yin et. Al analysed MWA response rates of lesions beyond the BCLC guidelines, with tumors measuring 3.0-5.0cm reported to have complete response rate of 95.4% and those measuring 5.0-7.0cm with a rate of 80%.[25] Similarly, a study by Kuang et al. reported promising complete response rates of 94%, 91% and 92% in tumors sized ≤3.0cm, 3.1cm-5.0cm and 5.1cm-8.0cm, respectively.[23]

LIMITATIONS

Although the data from our study is promising, our study included a small sample size. We did not include patients who had more than one session of MWA, nor did we include patients undergoing multimodality treatments, such as transarterial chemo-embolisation in combination with MWA. The addition of these patients would give us a wider perspective and more conclusive data on the overall survival of locoregionally treated HCC patients.

SUMMARY AND CONCLUSION

The use of MWA for treating very early and early stage HCC has been widely accepted owing to the minimally invasive nature of the procedure and good response rates. In this study, 34 HCC patients (total of 44 lesions) aged between 45-81 years underwent ultrasound guided percutaneous MWA. Alcohol was found to be the most common risk factor associated with cirrhosis, followed by hepatitis C virus infection and non-alcoholic steatohepatitis.

On a short term follow up, 87.5% LR-TR non-viable and 12.5% LR-TR viable lesions were reported at 3 months. In regard to the overall patient's response to MWA, assessed by mRECIST, complete response in 61.3%, progressive disease in 35.5% and stable disease in 3.2% were observed in 31 patients. A total of three deaths were reported, attributed to worsening liver decompensation and intra-tumoral bleed, post the ablation.The overall survival of patients undergoing MWA in our study was 91.2 % in three months duration.

Additionally, the application of MWA in intermediate stage HCC (3.0-5.0cm lesions) was found to be just as promising as very early and early stage HCC, with adequate complete response rates.

BIBLIOGRAPHY

1. Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2021;71:209–49.

2. Choi JY, Lee JM, Sirlin CB. CT and MR imaging diagnosis and staging of hepatocellular carcinoma: part I. Development, growth, and spread: key pathologic and imaging aspects. Radiology. 2014;272:635–54.

3. Omata M, Lesmana LA, Tateishi R, Chen PJ, Lin SM, Yoshida H, et al. Asian Pacific Association for the Study of the Liver consensus recommendations on hepatocellular carcinoma. Hepatol Int. 2010;4:439–74.

4. Chernyak V, Fowler KJ, Kamaya A, Kielar AZ, Elsayes KM, Bashir MR, et al. Liver Imaging Reporting and Data System (LI-RADS) version 2018: imaging of hepatocellular carcinoma in at-risk patients. Radiology. 2018;289:816–30.

5. Granata V, Fusco R, Avallone A, Catalano O, Filice F, Leongito M, et al. Major and ancillary magnetic resonance features of LI-RADS to assess HCC: an overview and update. Infect Agent Cancer. 2017;12:1–12.

6. Dhanasekaran R, Limaye A, Cabrera R. Hepatocellular carcinoma: current trends in worldwide epidemiology, risk factors, diagnosis, and therapeutics. Hepatic Med Evid Res. 2012;19–37.

7. Lencioni R, Cioni D, Crocetti L, Bartolozzi C. Percutaneous ablation of hepatocellular carcinoma: state-of-the-art. Liver Transpl. 2004;10:91–7.

8. Galle PR, Forner A, Llovet JM, Mazzaferro V, Piscaglia F, Raoul JL, et al. EASL clinical practice guidelines: management of hepatocellular carcinoma. J Hepatol. 2018;69:182–236.

9. Azam F, Latif MF, Farooq A, Tirmazy SH, AlShahrani S, Bashir S, et al. Performance status assessment by using ECOG (Eastern Cooperative Oncology Group) score for cancer patients by oncology healthcare professionals. Case Rep Oncol. 2019;12:728–36.

10. Pugh RNH, Murray-Lyon IM, Dawson JL, Pietroni MC, Williams R. Transection of the oesophagus for bleeding oesophageal varices. Br J Surg. 1973;60:646–9.

11. Vogl TJ, Nour-Eldin NEA, Hammerstingl RM, Panahi B, Naguib NN. Microwave ablation (MWA): basics, technique and results in primary and metastatic liver neoplasms–review article. In: RöFo-Fortschritte auf dem Gebiet der Röntgenstrahlen und der bildgebenden Verfahren. \copyright Georg Thieme Verlag KG; 2017;189;1055–66.

12. Sun Y, Cheng Z, Dong L, Zhang G, Wang Y, Liang P. Comparison of temperature curve and ablation zone between 915-and 2450-MHz cooled-shaft microwave antenna: results in ex vivo porcine livers. Eur J Radiol. 2012;81:553–7.

13. Marrero JA, Kulik LM, Sirlin CB, Zhu AX, Finn RS, Abecassis MM, et al. Diagnosis, S taging, and M anagement of H epatocellular C arcinoma: 2018 P ractice G uidance by the A merican A ssociation for the S tudy of L iver D iseases. Hepatology. 2018;68:723–50.

14. Ziemlewicz TJ, Hinshaw JL, Lubner MG, Brace CL, Alexander ML, Agarwal P, et al. Percutaneous microwave ablation of hepatocellular carcinoma with a gas-cooled system: initial clinical results with 107 tumors. J Vasc Interv Radiol. 2015;26:62–8.

15. Voizard N, Cerny M, Assad A, Billiard JS, Olivié D, Perreault P, et al. Assessment of hepatocellular carcinoma treatment response with LI-RADS: a pictorial review. Insights Imaging. 2019;10:1–22.

16. Lencioni R, Llovet JM. Modified RECIST (mRECIST) assessment for hepatocellular carcinoma. In: Seminars in liver disease. \copyright Thieme Medical Publishers; 2010;30;52–60.

17. Banda A, Johnson G, Cunha GM. Assessment of response to liver directed radiation-based therapies: Current guidelines, challenges, and future directions. Hepatoma Res. 2023;9:1.

18. Lü MD, Kuang M, Liang LJ, Xie XY, Peng BG, Liu GJ, et al. Surgical resection versus percutaneous thermal ablation for early-stage hepatocellular carcinoma: a randomized clinical trial. Zhonghua Yi Xue Za Zhi. 2006;86:801–5.

19. Chen MS, Li JQ, Zheng Y, Guo RP, Liang HH, Zhang YQ, et al. A prospective randomized trial comparing percutaneous local ablative therapy and partial hepatectomy for small hepatocellular carcinoma. LWW; 2006.

20. Bhardwaj N, Strickland AD, Ahmad F, Dennison AR, Lloyd DM. Liver ablation techniques: a review. Surg Endosc. 2010;24:254–65.

21. Ding J, Jing X, Liu J, Wang Y, Wang F, Wang Y, et al. Comparison of two different thermal techniques for the treatment of hepatocellular carcinoma. Eur J Radiol. 2013;82:1379–84.

22. Cucchetti A, Piscaglia F, Cescon M, Colecchia A, Ercolani G, Bolondi L, et al. Cost-effectiveness of hepatic resection versus percutaneous radiofrequency ablation for early hepatocellular carcinoma. J Hepatol. 2013;59:300–7.

23. Kuang M, Lu MD, Xie XY, Xu HX, Mo LQ, Liu GJ, et al. Liver cancer: increased microwave delivery to ablation zone with cooled-shaft antenna—experimental and clinical studies. Radiology. 2007;242:914–24.

24. Liang P, Wang Y, Yu X, Dong B. Malignant liver tumors: treatment with percutaneous microwave ablation—complications among cohort of 1136 patients. Radiology. 2009;251:933–40.

25. Yin XY, Xie XY, Lu MD, Xu HX, Xu ZF, Kuang M, et al. Percutaneous thermal ablation of medium and large hepatocellular carcinoma: long-term outcome and prognostic factors. Cancer. 2009;115:1914–23.

26. Livraghi T, Meloni F, Solbiati L, Zanus G, system CIG using A. Complications of microwave ablation for liver tumors: results of a multicenter study. Cardiovasc Intervent Radiol. 2012;35:868–74.

27. Giorgio A, Gatti P, Montesarchio L, Merola MG, Amendola F, Calvanese A, et al. Microwave Ablation in Intermediate Hepatocellular Carcinoma in Cirrhosis: An Italian Multicenter Prospective Study. J Clin Transl Hepatol. 2018;6:251–7.

28. Liu Y, Zheng Y, Li S, Li B, Zhang Y, Yuan Y. Percutaneous microwave ablation of larger hepatocellular carcinoma. Clin Radiol. 2013;68:21–6.

29. Wei H, Chivi S, Contractor S. Long-Term Survival of Large (≥ 3CM) Hepatocellular Carcinoma Treated with Microwave Ablation. Clin Oncol. 2017;2:1294.

30. Ma S, Ding M, Li J, Wang T, Qi X, Shi Y, et al. Ultrasound-guided percutaneous microwave ablation for hepatocellular carcinoma: clinical outcomes and prognostic factors. J Cancer Res Clin Oncol. 2017;143:131–42.

31. Darweesh SK, Gad AA. Percutaneous microwave ablation for HCV-related hepatocellular carcinoma: Efficacy, safety, and survival. Turk J Gastroenterol. 2019;30:445.

32. Wang X, Sofocleous CT, Erinjeri JP, Petre EN, Gonen M, Do KG, et al. Margin size is an independent predictor of local tumor progression after ablation of colon cancer liver metastases. Cardiovasc Intervent Radiol. 2013;36:166–75.

33. Kim JS, Kim W, So YH, Yu SJ, Kim BG. Topographical Impact of Hepatitis B-related Hepatocellular Carcinoma on Local Recurrence After Radiofrequency Ablation. J Clin Gastroenterol. 2014;48:66–72.

34. Filippiadis DK, Spiliopoulos S, Konstantos C, Reppas L, Kelekis A, Brountzos E, et al. Computed tomography-guided percutaneous microwave ablation of hepatocellular carcinoma in challenging locations: safety and efficacy of high-power microwave platforms. Int J Hyperthermia. 2018;34:863–9.

35. Soliman AF, Abouelkhair MM, Hasab Allah MS, El-Kady NM, Ezzat WM, Gabr HA, et al. Efficacy and Safety of Microwave Ablation (MWA) for Hepatocellular Carcinoma (HCC) in Difficult Anatomical Sites in Egyptian Patients with Liver Cirrhosis. Asian Pac J Cancer Prev. 2019;20:295–301.

36. An C, Cheng Z, Yu X, Han Z, Liu F, Li X, et al. Ultrasound-guided percutaneous microwave ablation of hepatocellular carcinoma in challenging locations: oncologic outcomes and advanced assistive technology. Int J Hyperthermia. 2020;37:89–100.

37. Roayaie K, Feng S. Allocation policy for hepatocellular carcinoma in the MELD era: Room for improvement? Liver Transpl. 2007;13:36–43.

38. Yao FY, Ferrell L, Bass NM, Bacchetti P, Ascher NL, Roberts JP. Liver transplantation for hepatocellular carcinoma: Comparison of the proposed UCSF criteria with the Milan criteria and the Pittsburgh modified TNM criteria. Liver Transpl. 2002;8:765–74.

39. Ioannou GN, Perkins JD, Carithers RL. Liver Transplantation for Hepatocellular Carcinoma: Impact of the MELD Allocation System and Predictors of Survival. Gastroenterology. 2008;134:1342–51.

40. Sharma P, Welch K, Hussain H, Pelletier SJ, Fontana RJ, Marrero J, et al. Incidence and Risk Factors of Hepatocellular Carcinoma Recurrence After Liver Transplantation in the MELD Era. Dig Dis Sci. 2012;57:806–12.

41. Baecker A, Liu X, La Vecchia C, Zhang ZF. Worldwide incidence of hepatocellular carcinoma cases attributable to major risk factors. Eur J Cancer Prev Off J Eur Cancer Prev Organ ECP. 2018;27:205–12.

42. Akinyemiju T, Abera S, Ahmed M, Alam N, Alemayohu MA, Allen C, et al. The burden of primary liver cancer and underlying etiologies from 1990 to 2015 at the global, regional, and national level: results from the global burden of disease study 2015. JAMA oncology. 2017;3:1683-91.

43. Conticchio M, Inchingolo R, Delvecchio A, Laera L, Ratti F, Gelli M, et al. Radiofrequency ablation vs surgical resection in elderly patients with hepatocellular carcinoma in Milan criteria. World J Gastroenterol. 2021;27:2205–18.

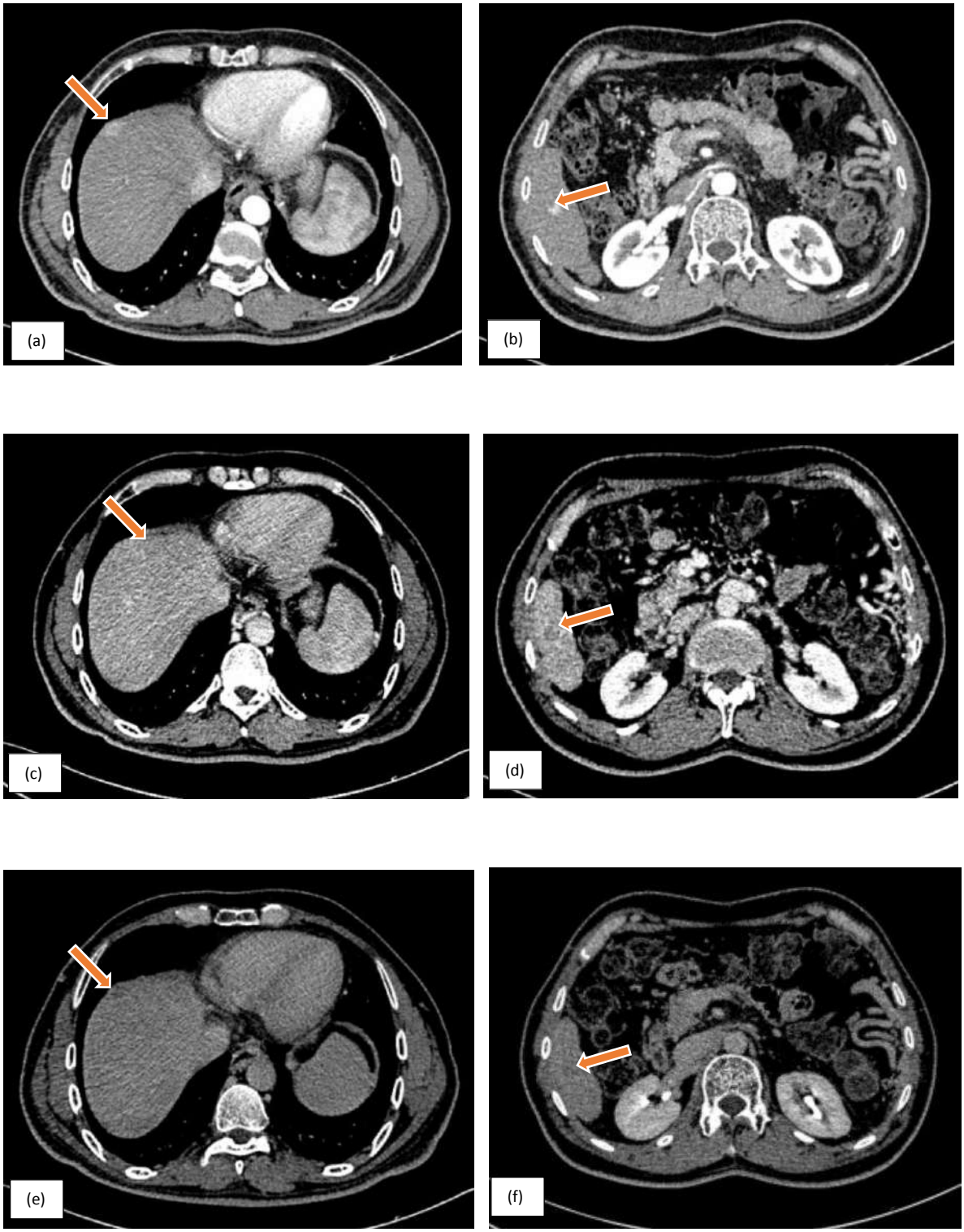
44. Renzulli M, Brandi N, Pecorelli A, Pastore LV, Granito A, Martinese G, et al. Segmental Distribution of Hepatocellular Carcinoma in Cirrhotic Livers. Diagn Basel Switz. 2022;12:834.

45. Joo I, Morrow KW, Raman SS, McWilliams JP, Sayre JW, Lu DS. CT-monitored minimal ablative margin control in single-session microwave ablation of liver tumors: an effective strategy for local tumor control. Eur Radiol. 2022;32:6327–35.

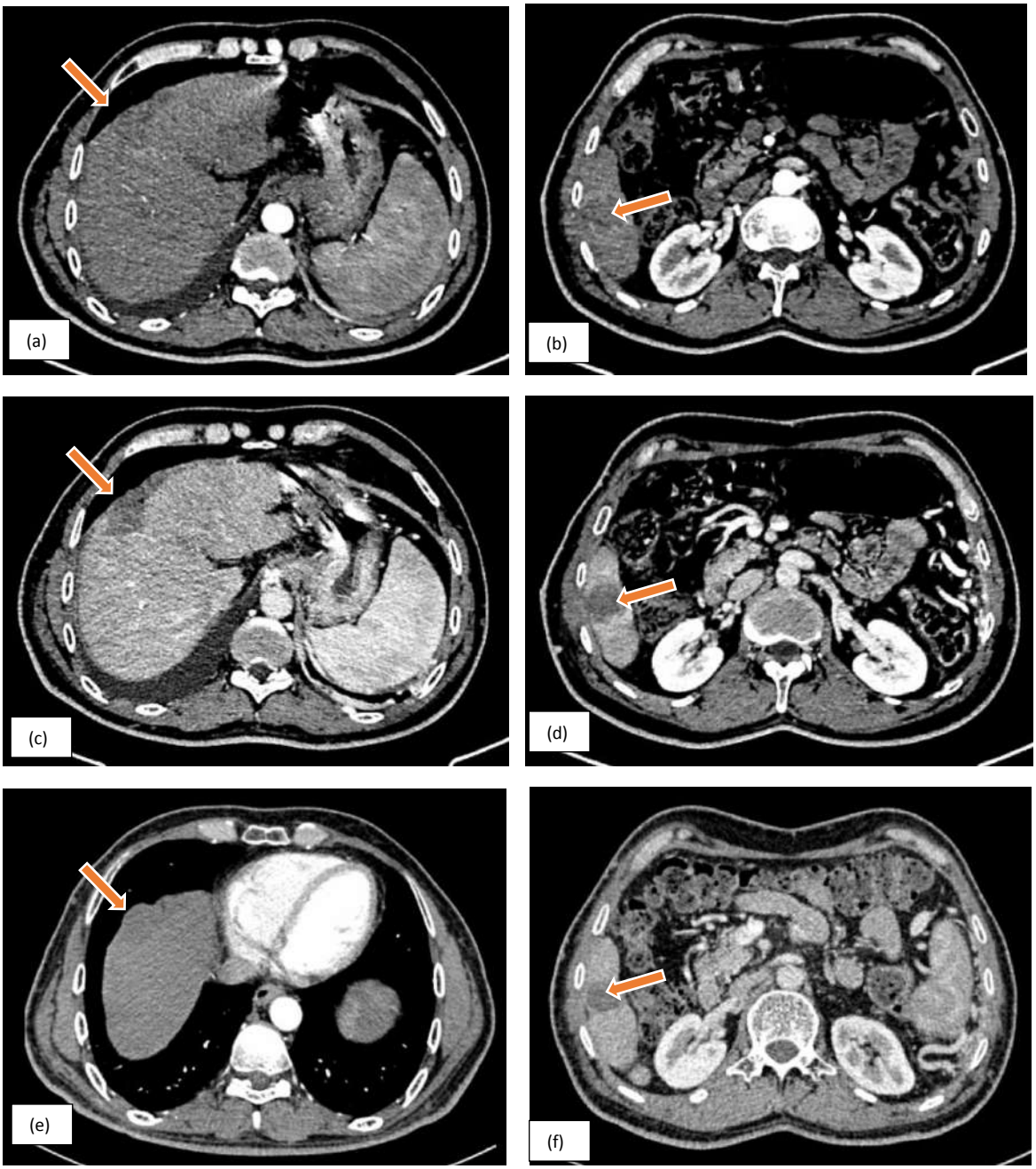
46. Kong WT, Zhang WW, Qiu YD, Zhou T, Qiu JL, Zhang W, et al. Major complications after radiofrequency ablation for liver tumors: analysis of 255 patients. World J Gastroenterol. 2009;15:2651–6.

47. Lee K fai, Wong J, Hui JW yi, Cheung Y sun, Chong CC ning, Fong AK wai, et al. Long-term outcomes of microwave versus radiofrequency ablation for hepatocellular carcinoma by surgical approach: A retrospective comparative study. Asian J Surg. 2017;40:301–8.

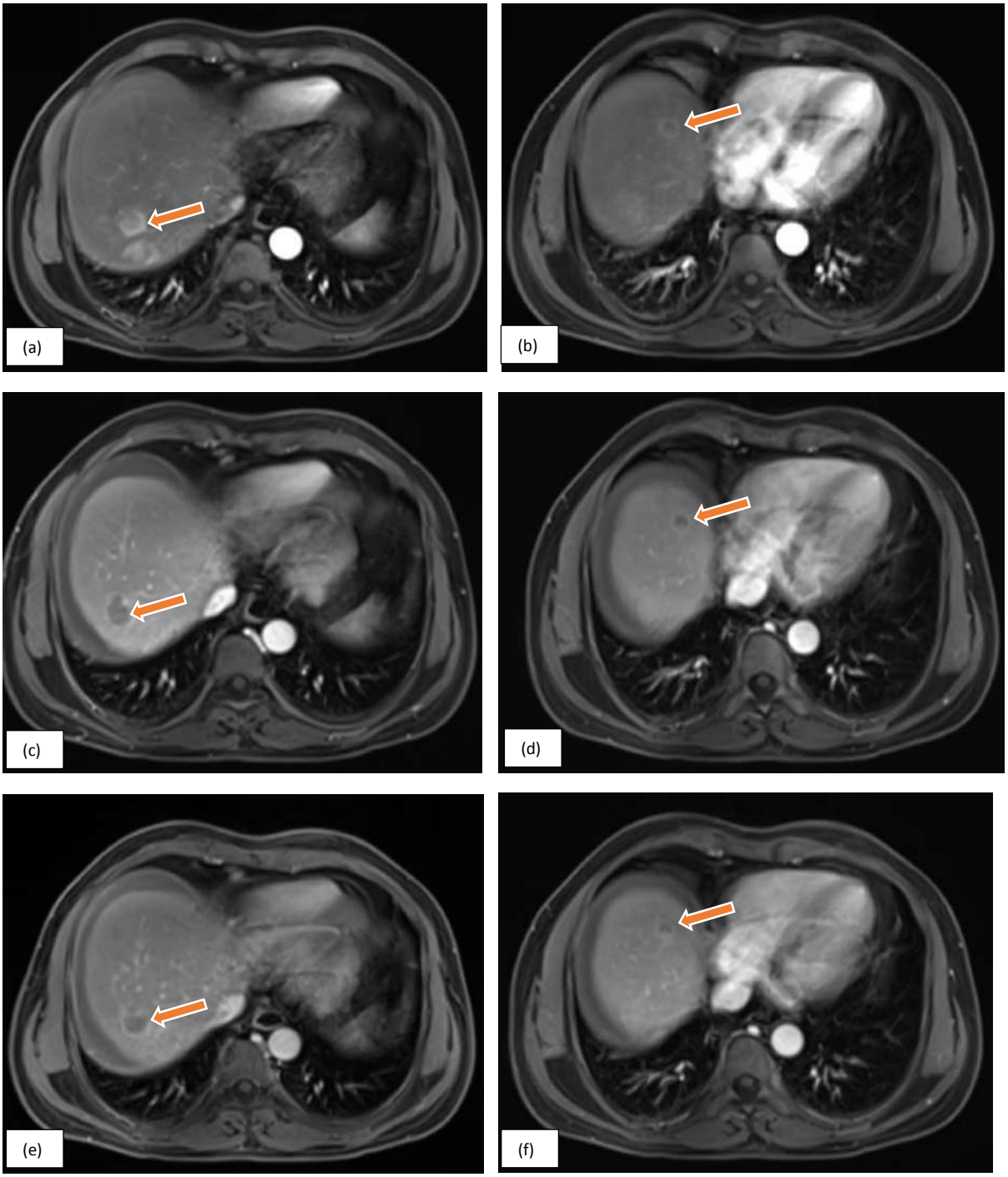
48. Liu W, Zheng Y, Zou R, Shen J, He W, Yang Z, et al. Impact of follow-up interval on patients with hepatocellular carcinoma after curative ablation. BMC Cancer. 2018;18:1–9.



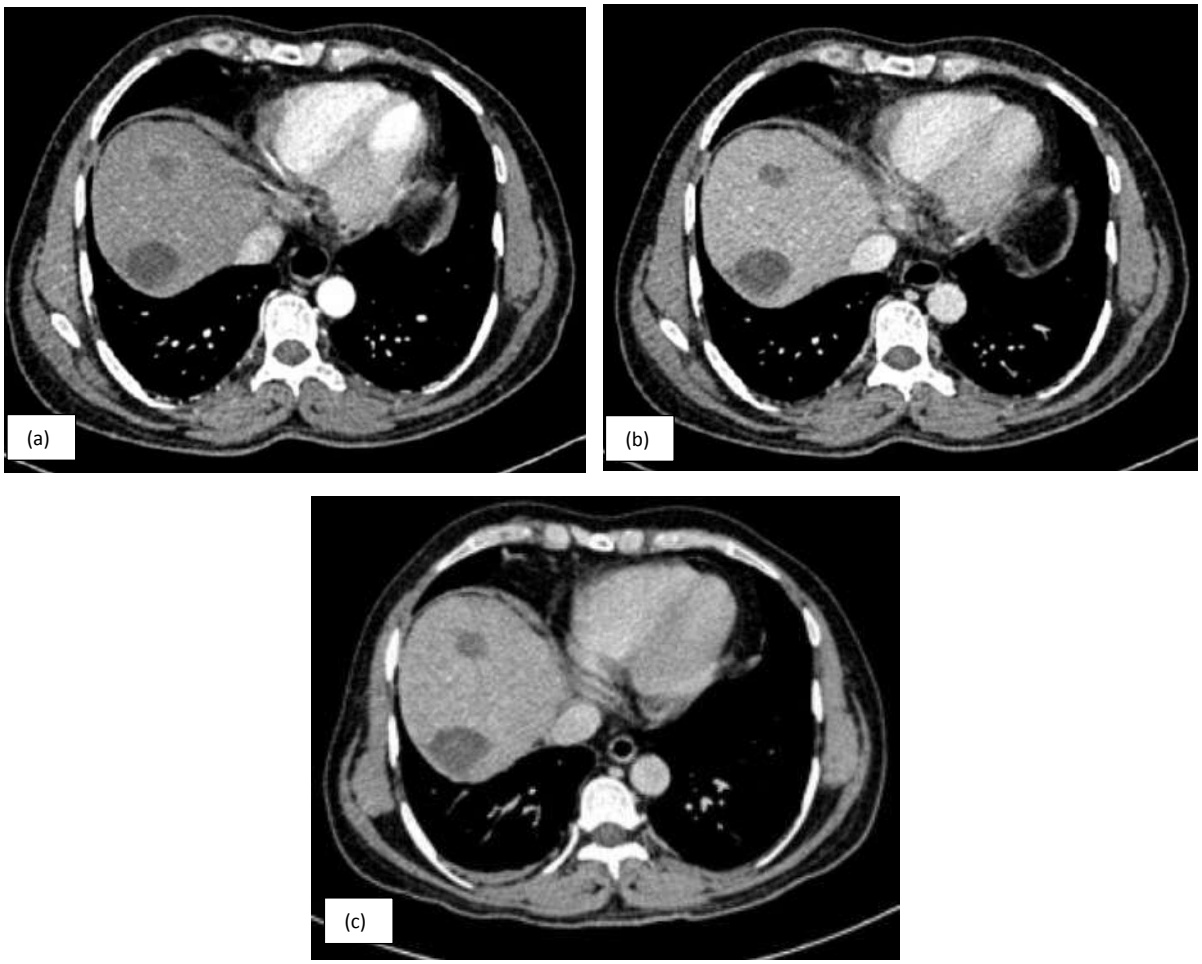
Picture 1: Case one- pre-ablation CT triphasic axial images showing arterially hyperenhancing lesions in segment VIII in the subcapsular location (a) and in segment VI (b) in the same patient. Venous phase images showing washout in the respective segments corresponding to the lesion (c) and (d). Delayed phase images also showing washout (e) and (f).



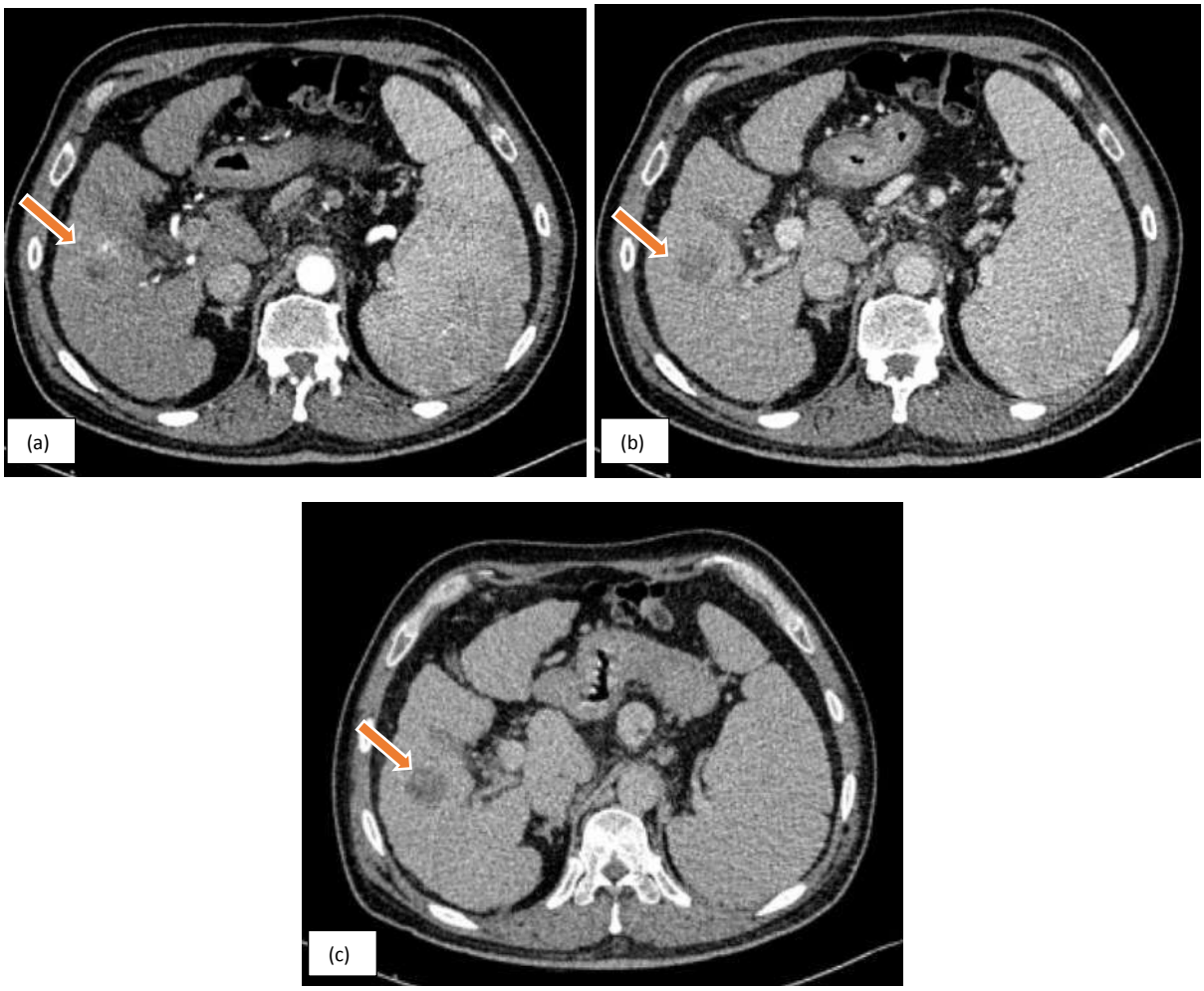
Picture 2: Case one-Post ablation CECT axial images showing the ablation cavities in segment VIII and VI appearing hypodense in all phases at 6 weeks follow up (a-d). On arterial phase images (a) and (b), mild peripheral enhancement is noted around the central hypodense ablation cavity, suggestive of hyperemia. Venous phase images (c) and (d) show hypodense ablation cavities with persistent surrounding hyperemia, and no washout. At 3 months follow up, the peri-ablation hyperemia has resolved in both the arterial (e) and venous phases (f)



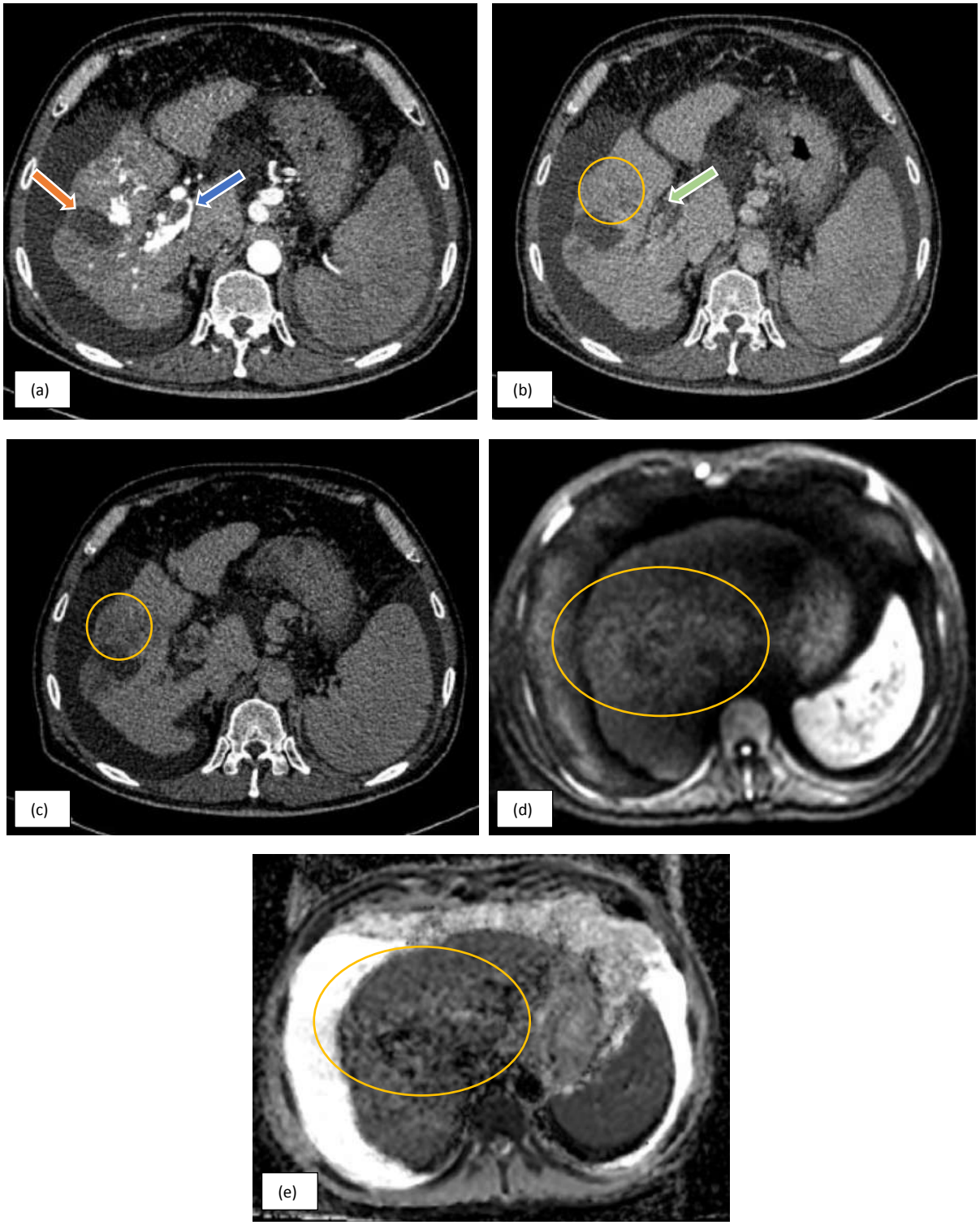
Picture 3: Case two – pre-ablation multiphasic MR axial images showing non-peripheral arterial hyperenhancement in segment VIII (a) and peripheral enhancement in segment IVa (b), in the same patient. On portal (c) (d) and venous phases (e) (f), washout is seen with enhancing capsule.



Picture 4: Case two - post-ablation axial CT triphasic images on follow up. Arterial (a), venous (b) and delayed (c) phases showing hypodense, non enhancing ablation cavities (LR-TR non viable).



Picture 5: Case three - pre-ablation CT triphasic axial images showing a heterogeneously enhancing lesion in segment V (a), which shows washout on venous (b) and delayed (c) images.



Picture 6: Case three- post ablation follow up imaging. CT triphasic axial images (a-c) and MRI DWI (d) and ADC (e) at 3 months follow up. Arterial phase (a) showing hypodense non-enhancing ablation cavity (orange arrow) and hypodense filling defect in right branch of portal vein (blue arrow), suggestive of thrombosis. On venous (b) and delayed (c) phases, there is evidence of a large area of washout in segment V surrounding the ablation cavity, suggestive of an infiltrative mass and washout of right portal vein thrombus implying a tumor in vein (green arrow). The same area shows patchy diffusion restriction on Axial MRI DWI (d) and ADC (e).

S.No._____

PROFORMA

ASSESSMENT OF TREATMENT RESPONSE TO MICROWAVE ABLATION IN HEPATOCELLULAR CARCINOMA

Date: _____

Biodata:

Name: _____

Age : _____ Sex : _____

MRD No: _____

Contact No: _____

Address: _____

Clinical History

Basic diagnosis: Normal liver CLD Cirrhosis

IF Cirrhosis:

Etiology: HCV HBV Alcoholic NASH

Family history of cirrhosis: Yes / No

IF HCV/HBV +

Viral load: Genotype:

Antiviral treatment: on treatment completed vaccinated

Viral status: response : present / absent

Ascites: Yes / No

Encephalopathy: Yes / No

Alcohol: YES/ NO Smoker: YES / NO Opium: YES/ NO

Presentation : Incidental pickup surveillance decompensated cirrhosis

Signature of Candidate **Signature of Supervisor**

S.No._____

GENERAL PHYSICAL EXAMINATION:

Vitals: HR _____ bpm

BP _____ mm/Hg

RR _____ cpm

SPO_2 _____ %

Pallor:

Oedema:

Jaundice:

Clubbing:

Cyanosis:

Investigations:

LFT	S. Bilirubin	mg/dl
	D. bilirubin	mg/dl
	SGOT	U/L
	SGPT	U/L
	T. Albumin	g/dl
	T. Proteins	g/dl
	Alk. Phosphate	U/L
AFP levels		
CBC	Hb	
	WBC	
	Platelets	
Coagulation Profile	PT / INR	
RFT	S. Creatinine	mg/dl
	S. Urea	mg/dl
	S. Na^+	mmol/L

CHILD - PUGH Score:
(T.bilirubin + INR + Albumin + Ascites + Encephalopathy)

MELD Score: (creatinine, bilirubin, INR)

Signature of Candidate

Signature of Supervisor

S.No._____

CT / MRI Findings:

IF Cirrhosis

Size

Liver

Spleen

Surface: Nodular Irregular

Left lobe hypertrophy:

Recanalization of Umbilical vein:

Vascular Thrombosis

Main PV Rt branch Lt Branch

SMV

Any other

IVC

Metastasis:

Ascites:

Any Collaterals

FNAC / BIOPSY result:

BCLC Stage:

Signature of Candidate **Signature of Supervisor**

S.No._____

Management:

Total number of MWA sittings: _____

	Lesion 1	Lesion 2	Lesion 3
Segment			
Size			
Arterial Enhancement			
Portal phase			
Venous phase			
MWA Ablation zone: Ablation time: Power:			

Signature of Candidate **Signature of Supervisor**

S.No._____

FOLLOW UP IMAGING (CECT / CEMR TRIPHASIC)			
	LESION 1	LESION 2	LESION 3
At 6 weeks interval Date:			
LI-RADS LR-TR Nonviable/equivocal/viable			
mRECIST Criteria (CR/PR/PD/SD)			
At 3 months interval Date:			
LI-RADS LR-TR Nonviable/equivocal/viable			
mRECIST Criteria (CR/PR/PD/SD)			
In case of death, the cause of death			

Signature of Candidate **Signature of Supervisor**

KEY TO MASTER CHART

MRD	Medical Registration Number
T.BILI	Total Bilirubin
D.BILI	Direct Bilirubin
SGOT	Serum glutamic-oxaloacetic acid
SGPT	Serum glutamic pyruvic transaminase
ALP	Alkaline Phosphatase
AFP	Alpha fetoptrotein
HB	Hemoglobin
WBC	White Blood Cell count
PLT	Platelet count
PT/INR	Prothrombine Time / International Normalised Ratio
S.CREAT	Serum Creatinine
S.UREA	Sreum Urea
S.Na+	Setum Sodium
MELD	Model for End stage Liver Disease score
BCLC	Barcelona Chronic Clinic Liver Cancer
FNAC	Fine Needle Aspiration Cytology
BX	Biopsy
APHE	Arterial Phase Hyperenhancement
Wks	Weeks
Mnth	Months

S.NO	DATE	NAME	AGE	SEX	MRD	CONTACT NO	BASIC DIAGNOSIS	IF CIRRHOSIS	ASCITES	ENCEPHAL OPATHY	ALCOHOL	SMOKER	OPIUM	T.BILI	D.BILI	SGOT	SGPT	T. ALBUMIN
1	12-07-2021	MS	45	M	132915	9872536835	CIRRHOSIS	HCV	YES	NO	NO	NO	NO	1.01	0.4	42	61	4.01
2	14-10-2021	NS	65	M	1188711	9888338003	CIRRHOSIS	HCV, ALCOHOL	YES	NO	YES	NO	NO	0.67	0.23	38	53	3.7
3	22-02-2021	SK	47	M	938019	9815936717	CIRRHOSIS	ALCOHOL	YES	NO	YES	NO	NO	2.9	1	81	28	2.9
4	09-02-2021	SL	78	M	1019147	9815812323	CIRRHOSIS	HCV	NO	NO	NO	NO	NO	2	1.6	168	82	2.9
5	06-08-2021	KK	55	F	29233	9915122134	CIRRHOSIS	NASH	YES	NO	NO	NO	NO	1.68	0.8	40	18	3.8
6	20-07-2021	ST	60	M	184974	9356561144	CIRRHOSIS	HCV, ALCOHOL	YES	NO	YES	YES	YES	2.2	0.63	33	25	3.14
7	13-12-2021	JS	56	M	1218784	9878788105	CIRRHOSIS	HBV	YES	NO	NO	NO	NO	1.45	0.98	62	29	2.56
8	10-04-2021	GS	56	M	428361	9417909861	CIRRHOSIS	HCV	NO	NO	NO	NO	NO	0.8	0.39	75	66	4.15
9	28-09-2021	GS	79	M	1179933	9815288336	CIRRHOSIS	ALCOHOL	NO	NO	YES	NO	NO	0.7	0.34	56	26	3.3
10	27-03-2021	VV	69	M	1061610	9876319222	CLD	ALCOHOL	NO	NO	YES	NO	NO	0.37	0.28	32	19	3.2
11	23-04-2021	MS	51	M	1034137	8360928013	CIRRHOSIS	NASH	YES	NO	NO	NO	NO	1.21	0.43	35	17	3.12
12	23-07-2021	ND	66	F	1138000	9646309022	CIRRHOSIS	NASH	YES	NO	NO	NO	NO	0.45	0.22	42	38	3.6
13	14-10-2021	BSD	60	M	1190593	9501124103	CIRRHOSIS	ALCOHOL	NO	NO	YES	NO	NO	0.46	0.11	28	32	4.07
14	15-07-2021	MS	54	M	1134142	9988280711	CIRRHOSIS	NASH	NO	NO	NO	NO	NO	1.36	0.34	103	79	3.8
15	28-05-2021	VP	56	M	706413	9814618898	CLD	HBV	NO	NO	NO	NO	NO	0.49	0.27	33	26	3.26
16	01-07-2021	MS	67	M	1129163	9501019458	CIRRHOSIS	NASH	NO	NO	NO	NO	NO	1.23	0.44	31	25	3.86
17	21-07-2021	VKG	71	M	1137754	9463357845	CIRRHOSIS	ALCOHOL	NO	NO	YES	YES	NO	0.44	0.13	201	132	3.79
18	19-11-2021	GK	66	F	50336	9876273170	CIRRHOSIS	HCV	NO	NO	NO	NO	NO	2	0.5	212	97	2.89
19	21-09-2021	DS	53	M	1140560	9872693598	CIRRHOSIS	ALCOHOL	YES	NO	YES	YES	YES	1.9	1	92	57	2
20	16-07-2021	SS	73	F	641669	9814054553	CIRRHOSIS	NASH	NO	NO	NO	NO	NO	1	0.22	86	36	3.43
21	16-11-2021	KS	71	M	1200217	9781653478	CIRRHOSIS	HCV	NO	NO	NO	NO	NO	0.57	0.23	19	20	3.83
22	09-11-2021	CL	71	M	234553	8283051783	CIRRHOSIS	HBV, ALCOHOL	NO	NO	YES	YES	NO	0.46	0.2	31	17	4.3
23	07-10-2021	HK	69	F	180117	9779070470	CIRRHOSIS	HCV	YES	NO	NO	NO	NO	0.77	0.16	39	27	4.08
24	14-07-2021	VPD	72	M	940257	9814912362	CIRRHOSIS	ALCOHOL	YES	NO	YES	YES	NO	1.5	1.03	25	11	3.1
25	08-09-2021	BS	63	M	1162884	7837470751	CIRRHOSIS	ALCOHOL	YES	NO	YES	NO	NO	2.07	1.39	79	42	3.49
26	04-09-2021	RK	62	M	1145734	9041263004	CIRRHOSIS	ALCOHOL	YES	NO	YES	NO	NO	0.84	0.17	37	16	3.87
27	30-04-2022	AS	46	M	1236781	7983954051	CIRRHOSIS	ALCOHOL	NO	NO	YES	YES	YES	1.26	0.61	54	44	3.7
28	01-11-2021	RK	63	M	217864	9915525620	CIRRHOSIS	HCV	NO	NO	NO	NO	NO	2.21	0.57	47	42	2.7
29	12-06-2022	SRG	81	F	1076314	9872099777	CIRRHOSIS	NASH	NO	NO	NO	NO	NO	0.2	0.06	40	20	3.5
30	06-05-2022	R	62	M	827766	9814811241	CIRRHOSIS	HCV	NO	NO	NO	NO	NO	1.7	0.54	48	32	4.2
31	06-05-2022	RK	62	M	689076	9878670753	CIRRHOSIS	ALCOHOL	NO	NO	YES	NO	NO	0.5	0.11	41	54	3.99
32	18-04-2022	HS	63	M	1095138	8421781679	CLD	ALCOHOL	YES	NO	YES	NO	NO	2.86	2.17	232	68	2.9
33	29-03-2022	GR	60	M	966261	9419239361	CIRRHOSIS	ALCOHOL	NO	NO	YES	YES	NO	1.21	0.81	45	48	3.4
34	03-02-2022	SS	54	M	334842	8427621358	CIRRHOSIS	NASH	YES	NO	NO	NO	NO	0.53	0.25	156	87	3.8

S.NO	T. PROTEIN	ALP	AFP	HB	WBC	PLT	PT/INR	S. CREAT	S. UREA	S. NA+	CHILD-PUGH	MELD	BCLC	FNAC/BX
1	6.8	78	6.81	13.7	5.6	140	1.24	0.61	21	141	CLASS B	9	STAGE B	NO
2	7.6	93	4.27	5.2	10	250	1.08	1.65	86	140	CLASS B	12	STAGE B	NO
3	6.2	180	150.34	7.7	2.1	90	1.56	0.57	11	133	CLASS B	18	STAGE B	NO
4	6.5	263	888	11.9	5.9	110	1.4	1.19	32	138	CLASS A	14	STAGE A	NO
5	7.3	145	.	9.1	1.8	46	1.5	0.89	29	138	CLASS B	13	STAGE O	NO
6	8	157	8.5	3.2	3.2	71	1.36	0.7	21	121	CLASS B	24	STAGE A	NO
7	6.4	151	8.5	8.8	4.4	62	1.4	0.76	22	137	CLASS B	12	STAGE A	NO
8	7.1	111	.	12.8	3.5	50	1.06	0.71	24	138	CLASS A	7	STAGE A	NO
9	6.5	178	4.74	12	5.2	131	1	0.98	24	135	CLASS A	6	STAGE A	NO
10	6.7	179	53.32	10.1	5.9	160	1.07	1.49	45	138	CLASS A	11	STAGE A	NO
11	6.7	126		11.5	3.7	108	1.29	0.7	37	140	CLASS B	10	STAGE A	NO
12	6.5	167	267	12.7	4.1	60	1.18	0.24	18	139	CLASS A	8	STAGE A	NO
13	7.6	158	.	9.3	6.9	150	1.1	0.84	34	130	CLASS A	7	STAGE A	NO
14	7.7	109	.	11.8	4.5	140	1.3	0.5	17	137	CLASS A	11	STAGE A	NO
15	5.9	116	.	11.2	2.5	50	1.18	0.59	21	40	CLASS A	8	STAGE A	NO
16	7	97	11.7	12.5	7.9	90	1.18	0.96	21	139	CLASS A	10	STAGE A	NO
17	6.6	69	4.84	11.1	9.7	245	1	1.03	40	139	CLASS A	7	STAGE A	NO
18	5.4	112	6.47	12.1	5.1	154	1.31	0.39	28	141	CLASS B	12	STAGE A	NO
19	5.8	129	2.62	9.9	6.2	90	1.98	0.53	22	133	CLASS B	20	STAGE B	NO
20	6.4	74	6.6	11.4	3.4	52	1.1	0.63	25	142	CLASS A	7	STAGE O	NO
21	6.7	88	2.28	13.9	7.5	136	1.05	1.24	31	142	CLASS A	9	STAGE A	NO
22	7.3	88	.	12.4	5.7	156	1.17	0.88	24	139	CLASS A	8	STAGE B	NO
23	7.4	65	.	14.4	4.9	90	1.24	0.47	23	139	CLASS A	9	STAGE O	NO
24	6.3	135	.	10	3.3	70	1.4	0.78	19	135	CLASS B	14	STAGE B	NO
25	6.9	140	.	10.5	3.6	80	1.41	0.74	20	137	CLASS A	13	STAGE B	NO
26	7.5	121	.	9.4	3.1	98	1.21	1.28	39	135	CLASS A	9	STAGE B	NO
27	8.1	131	12.09	13	7.9	120	1.23	0.82	20	143	CLASS A	10	STAGE B	NO
28	5.7	206	193	12.6	5.8	97	1.21	0.45	20	141	CLASS B	12	STAGE B	NO
29	6.8	88	.	10.5	7.4	189	1.28	0.83	31	134	CLASS A	9	STAGE B	NO
30	7.6	108	9	13.7	3.9	61	1.26	0.66	21	138	CLASS A	11	STAGE B	NO
31	6.8	75	8.08	13.7	8.3	159	1.18	0.68	28	140	CLASS A	9	STAGE A	NO
32	7.2	158	86.3	9.5	4.3	65	1.45	0.68	15	138	CLASS B	15	STAGE B	NO
33	6.8	89	.	8.5	2	50	1.3	1.17	28	140	CLASS A	12	STAGE A	NO
34	6.3	103	.	9.8	5.2	62	1.09	0.95	31	134	CLASS B	7	STAGE B	NO

S.NO	NAME	AGE	SEX	MRD	NO.OF LESIONS	LESION 1												
						SEGMENT	SIZE (cm)	APHE	PORTAL	VENOUS	LIRADS	MWA ZONE (cm)	MWA TIME	POWER	SEGMENT	SIZE (cm)	APHE	PORTAL
1	MS	45	M	1132915	3	III	3.2 X 2.6	YES	WASHOUT	WASHOUT	V	4.2 X 3.6	10 MIN	100 W	VII	1.9 X 1.8	YES	WASHOUT
2	NS	65	M	1188711	1	VI	5.0 X 5.0	YES	WASHOUT	WASHOUT	V	5.5 X 5.4	15 MIN	100W	0	0	0	0
3	SK	47	M	938019	1	IV A	1.8 X 1.2	YES	WASHOUT	WASHOUT	V	3.4 X 2.9	2 MIN	100W	0	0	0	0
4	SL	78	M	1019147	2	VI	3.2 X 3.0	YES	WASHOUT	WASHOUT	V	4.2 X 3.6	10 MIN	100W	IV B	2.6 X 2.2	YES	WASHOUT
5	KK	55	F	29233	1	VIII	1.1 X 1.3	YES	WASHOUT	WASHOUT	V	3.4 X 2.9	2 MIN	100W	0	0	0	0
6	ST	60	M	184974	1	V	2.7 X 2.7	YES	WASHOUT	WASHOUT	V	3.3 X 3.9	5 MIN	100W	0	0	0	0
7	JS	56	M	1218784	1	VI	3.0 X 2.8	YES	WASHOUT	WASHOUT	V	3.9 X 3.4	5MIN	100W	0	0	0	0
8	GS	56	M	428361	2	VIII	1.5 X 1.2	YES	WASHOUT	WASHOUT	V	3.4 X 2.9	2 MIN	100W	VI	0.8 X 0.8	YES	WASHOUT
9	GS	79	M	1179933	1	VII	3.1 X 2.8	YES	WASHOUT	WASHOUT	V	4.5 X 3.9	13 MIN	100W	0	0	0	0
10	VV	69	M	1061610	1	VI	2.0 X 2.3	YES	WASHOUT	WASHOUT	V	3.7 X 3.5	5 MIN	100W	0	0	0	0
11	MS	51	M	1034137	1	VI	3.2 X 2.3	YES	WASHOUT	WASHOUT	V	3.5 X 3.2	5 MIN	100W	0	0	0	0
12	ND	66	F	1138000	1	VI	3.0 X 2.8	YES	WASHOUT	WASHOUT	V	3.5 x 3.2	5 MIN	100W	0	0	0	0
13	BSD	60	M	1190593	1	VIII	2.5 X 2.3	YES	WASHOUT	WASHOUT	V	3.1 X 3.7	3 MIN	100W	0	0	0	0
14	MS	54	M	1134142	1	VII	3.7 X 3.5	YES	WASHOUT	WASHOUT	V	4.5 X 3.9	13 MIN	100W	0	0	0	0
15	VP	56	M	706413	1	VI	1.4 X 1.3	YES	WASHOUT	WASHOUT	V	2.8 X 2.3	1MIN	100W	0	0	0	0
16	MS	67	M	1129163	1	V	4.6 X 4.6	YES	WASHOUT	WASHOUT	V	5.5 X 5.4	15MIN	100W	0	0	0	0
17	VKG	71	M	1137754	2	I	2.3 X 2.1	YES	WASHOUT	WASHOUT	V	3.7 X 3.1	3 MIN	100W	V	0.9 X 0.8	YES	WASHOUT
18	GK	66	F	50336	1	IV B	1.3 X 1.3	YES	WASHOUT	WASHOUT	V	3.1 X 3.7	3 MIN	100W	0	0	0	0
19	DS	53	M	1140560	1	VII	4.9 X 4.8	YES	WASHOUT	WASHOUT	V	5.5 X 5.4	15 MIN	100W	0	0	0	0
20	SS	73	F	641669	1	IV A	1.1 X 0.9	YES	WASHOUT	WASHOUT	V	3.4 X 2.9	2 MIN	100W	0	0	0	0
21	KS	71	M	1200217	1	VI	2.9 X 2.8	YES	WASHOUT	WASHOUT	V	3.9 X 3.4	5 MIN	100W	0	0	0	0
22	CL	71	M	234553	1	II/III	3.4 X 3.1	YES	WASHOUT	WASHOUT	V	4.5 X 3.9	13MIN	100W	0	0	0	0
23	HK	69	F	180117	1	VI	1.7 x 2.0	YES	WASHOUT	WASHOUT	V	2.9 X 3.4	2 MIN	100W	0	0	0	0
24	VPD	72	M	940257	3	VI	3.2 X 3.0	YES	WASHOUT	WASHOUT	V	4.5 X 3.9	13 MIN	100W	II	2.3 X 2.0	YES	NO
25	BS	63	M	1162884	1	VIII	4.0 X 3.8	YES	WASHOUT	WASHOUT	V	4.5 X 3.9	13 MIN	100W	0	0	0	0
26	RK	62	M	1145734	3	II	1.7 X 1.4	YES	WASHOUT	WASHOUT	V	3.1 X 3.7	3 MIN	100W	VIII	3.1 X 2.4	YES	WASHOUT
27	AS	46	M	1236781	2	I	2.0 X 1.7	YES	WASHOUT	WASHOUT	V	3.4 X 2.9	2 MIN	100W	VI	1.3 X 0.8	YES	WASHOUT
28	RK	63	M	217864	1	V/VI	4.9 X 4.7	YES	WASHOUT	WASHOUT	V	5.5 X 5.4	15 MIN	100W	0	0	0	0
29	SRG	81	F	1076314	1	IV	5.0 X 4.8	YES	WASHOUT	WASHOUT	V	5.5 X 5.4	15 MIN	100W	0	0	0	0
30	R	62	M	827766	1	VI/VII	2.1 X 1.5	YES	WASHOUT	WASHOUT	V	3.4 X 2.9	2 MIN	100W	0	0	0	0
31	RK	62	M	689076	1	VIII	2.4 X 2.4	YES	WASHOUT	WASHOUT	V	3.1 X 3.7	3 MIN	100W	0	0	0	0
32	HS	63	M	1095138	1	V	3.9 X 3.1	YES	WASHOUT	WASHOUT	V	4.5 X 3.9	13 MIN	100W	0	0	0	0
33	GR	60	M	966261	1	VII	1.6 X 1.6	YES	WASHOUT	WASHOUT	V	2.9 X 3.4	2 MIN	100W	0	0	0	0
34	SS	54	M	334842	2	VIII	2.3 X 2.0	YES	WASHOUT	WASHOUT	V	3.7 X 3.5	5 MIN	100W	0	0	0	0

S.NO	LESION 2					LESION 3									LESI
	VENOUS	LIRADS	MWA ZONE (cm)	MWA TIME	POWER	SEGMENT	SIZE (cm)	APHE	PORTAL	VENOUS	LIRADS	MWA ZONE (cm)	MWA TIME	POWER	LR-TR 6 Wks
1	WASHOUT	V	3.4 X 2.9	2 MIN	100W	IV A	1.1 X 1.0	YES	WASHOUT	WASHOUT	V	3.4 X 2.9	2 MIN	100W	LR-TR NONVIABLE
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	WASHOUT	V	3.7 X 3.1	3 MINS	100W	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR VIABLE
6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NON VIABLE
7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LT-TR NONVIABLE
8	WASHOUT	IV	2.3 X 2.8	1 MIN	100W	0	0	0	0	0	0	0	0	0	LR-TR EQUIVOCAL
9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NON VIABLE
10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR- TR NON VIABLE
11	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NON VIABLE
12	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NON VIABLE
13	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NON VIABLE
14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NON VIABLE
15	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NON VIABLE
16	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NON VIABLE
17	WASHOUT	IV	2.3 X 2.8	1 MIN	100W	0	0	0	0	0	0	0	0	0	LR-TR NON VIABLE
18	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NON VIABLE
19	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NON VIABLE
20	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR- TR NON VIABLE
21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NONVIABLE
22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NONVIABLE
23	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NON VIABLE
24	NO	IV	3.9 X 3.4	5 MIN	100W	VI	1.5 X 1.2	YES	WASHOUT	WASHOUT	V	2.8 X 2.3	1MIN	100 W	LR-TR NONVIABLE
25	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NONVIABLE
26	WASHOUT	V	4.5 X 3.9	13MIN	100W	VIII	1.3 X 1.3	YES	WASHOUT	WASHOUT	V	3.4 X 2.9	2 MIN	100W	LR-TR NONVIABLE
27	WASHOUT	V	2.3 X 2.8	1 MIN	100W	0	0	0	0	0	0	0	0	0	LT-TR NONVIABLE
28	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LT-TR NONVIABLE
29	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NONVIABLE
30	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NONVIABLE
31	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NONVIABLE
32	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NONVIABLE
33	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NONVIABLE
34	0	0	0	0	0	0	0	0	0	0	0	0	0	0	LR-TR NONVIABLE

S.NO	ON 1	LESION 2		LESION 3		Comments	mRECIST	
	LR-TR 3 months	LR-TR 6 Wks	LR-TR 3 mnth	LR-TR 6 Wks	LR-TR 3 mnth		at 6weeks	at 3 months
1	LR-TR NONVIABLE	LR-TR NONVIABLE	LR-TR NONVIABLE	LR-TR NONVIABLE	LR-TR NONVIABLE		CR	CR
2	0	0	0	0	0	Death: bleed in post-ablation cavity	0	0
3	0	0	0	0	0	Death: Decompensated cirrhosis	0	0
4	0	0	0	0	0	Death: hepatic encephalopathy like symptoms	0	0
5	LR-TR VIABLE	0	0	0	0	2 new lesions at 6 weeks	PD	PD
6	LR-TR VIABLE	0	0	0	0	Infiltrative mass around ablation zone at 3months	CR	PD
7	LR-TR NONVIABLE	0	0	0	0	3 new lesions at 6 weeks and multiple at 3months	PD	PD
8	LR-TR NONVIABLE	LR-TR NONVIABLE	LR-TR NONVIABLE	0	0		CR	CR
9	LR-TR NONVIABLE	0	0	0	0		CR	CR
10	LR-TR NONVIABLE	0	0	0	0	new lesion at 3 months	CR	PD
11	LR-TR NONVIABLE	0	0	0	0	new leasion at 6 weeks	PD	PD
12	LR-TR NONVIABLE	0	0	0	0		CR	CR
13	LT-TR NONVIABLE	0	0	0	0		CR	CR
14	LR-TR NONVIABLE	0	0	0	0	new lesion at 6 weeks	PD	PD
15	LR-TR NONVIABLE	0	0	0	0		CR	CR
16	LR-TR NONVIABLE	0	0	0	0		CR	CR
17	LR-TR NONVIABLE	LR-TR NONVIABLE	LR-TR NONVIABLE	0	0		CR	CR
18	LR-TR NONVIABLE	0	0	0	0		CR	CR
19	LR-TR NONVIABLE	0	0	0	0		CR	CR
20	LR-TR NONVIABLE	0	0	0	0		CR	CR
21	LR-TR NONVIABLE	0	0	0	0		CR	CR
22	LR-TR NONVIABLE	0	0	0	0		CR	CR
23	LR-TR NON VIABLE	0	0	0	0		CR	CR
24	LR-TR NONVIABLE	LR-TR VIABLE	LR-TR VIABLE	LR-TR VIABLE	LR-TR VIABLE		SD	SD
25	LR-TR NONVIABLE	0	0	0	0		CR	CR
26	LR-TR NONVIABLE	LR-TR NONVIABLE	LR-TR NONVIABLE	LR-TR NONVIABLE	LR-TR NONVIABLE		CR	CR
27	LR-TR NONVIABLE	LR-TR NONVIABLE	LR-TR NONVIABLE	0	0	new lesion in seg VIII at 6 weeks and multiple at 3 months	PD	PD
28	LT-TR NONVIABLE	0	0	0	0		CR	CR
29	LT-TR NONVIABLE	0	0	0	0		CR	CR
30	LR-TR NONVIABLE	0	0	0	0	multiple new lesions in right lobe at 6weeks	PD	PD
31	LR-TR VIABLE	0	0	0	0	one new lesion at 3 months	CR	PD
32	LR-TR NONVIABLE	0	0	0	0		CR	CR
33	LR-TR NONVIABLE	0	0	0	0	one new lesion at 3 months	CR	PD
34	LR-TR NONVIABLE	0	0	0	0	one new lesion at 3 months	CR	PD

Baba Farid University
of Health Sciences
Sadiq Road
Faridkot-151 203 (Pb.) INDIA.
Phone : 01639-256232,256236
Tele/Fax : 01639-256235
Email Examination@bfuhs.ac.in

No. BFUHS/2K21p-TH/ 128 Date 5/11/21

The Principal,
DMC, Ludhiana.

Subject: **Approval of Plan of Thesis.**

This is to inform you that the Faculty of Medical Sciences in its meeting held on 29.10.2021 has approved the plan of thesis of **Shivani Khant**, a student of your college for **MD Radio-diagnosis** along with the names of Supervisor/Co-Supervisor as under:-

Topic Plan of Thesis
Assessment of treatment response to microwave ablation in hepatocellular carcinoma.

Supervisor
Dr. Siddharth Prakash
Assoc. Prof.,
Dept. of Radio-diagnosis,
DMCH, Ludhiana.

Co-Supervisor

Dr. Ajit Sood
Prof. & Head,
Dept. of Gastroenterology,
DMCH, Ludhiana.

Dr. Chandan Kakkar
Assoc. Prof.,
Dept. of Radio-diagnosis,
DMCH, Ludhiana.

The student has to submit the four copies of thesis (along with PDF format) , to the Controller of Examinations, BFUHS, Faridkot, at least six months before the commencement of theory examination, if he/she is otherwise eligible to take the examination. He /She must directed to attach a photocopy of this letter with the forwarding letter while submitting thesis to the University along with the letter of approval of University for change of supervisor/Co-Supervisor, change of topic,(if any).

S P Singh

Dr. S P Singh MS(Oph)
Controller of Examinations

Note :

119. If any discrepancy found regarding topic of thesis or Supervisor/Co-Supervisor, inform undersigned within one month after issue of this letter.

120. The student may submit the thesis as per the schedule already conveyed i.e for May/June examination 30th Nov of the preceding the year of examination and for Nov/Dec examinations 31st May of the year of examination.

ASSESSMENT OF TREATMENT RESPONSE TO MICROWAVE ABLATION IN HEPATOCELLULAR CARCINOMA

THESIS PROPOSAL

FOR APPROVAL OF SUBJECT OF THESIS TO BE SUBMITTED IN

PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

MD

In

RADIODIAGNOSIS

OF THE

BABA FARID UNIVERSITY OF HEALTH SCIENCES

FARIDKOT

March, 2021

Dr. Shivani Khant

DEPARTMENT OF RADIODIAGNOSIS
DAYANAND MEDICAL COLLEGE AND HOSPITAL
LUDHIANA

ABSTRACT OF PLAN OF THESIS

TITLE	ASSESSMENT OF TREATMENT RESPONSE TO MICROWAVE ABLATION IN HEPATOCELLULAR CARCINOMA
THE DEGREE OF	MD RADIO-DIAGNOSIS
NAME OF THE CANDIDATE	DR. SHIVANI KHANT
SUPERVISOR	DR. SIDDHARTH PRAKASH, Associate professor, Department of Radiology, DMCH
CO-SUPERVISOR	DR. AJIT SOOD, Professor and head, Department of Gastroenterology, DMCH
CO-SUPERVISOR	DR. CHANDAN KAKKAR, Associate professor, Department of Radiology, DMCH
INSTITUTION	Dayanand Medical College & Hospital, Ludhiana
UNIVERSITY	Baba Farid University of Health Sciences, Faridkot

Introduction: Hepatocellular carcinoma (HCC) is the most common type of primary liver cancer, and the fifth most common carcinoma globally[1]. The radical cure for HCC is surgical excision or liver transplantation; however, very few cases are diagnosed early, hence the need for tumor ablation therapies arose. As the technology and expertise improve, microwave ablation (MWA) is emerging to be more advantageous to radiofrequency ablation (RFA) in treating HCC, owing to higher temperatures, shorter ablation time, and less heat sink effect [1]. Based on the aforesaid developments, this study explores the response to MWA on HCC lesions < 5cm, with special attention to lesions between 3-5cm.

Aim of Study: To assess the outcome of hepatocellular carcinoma lesions that are treated with microwave ablation.

Materials & methods:

An observational prospective study will be conducted on patients undergoing MWA for radiologically proven HCC, at the Department of Radiodiagnosis, Dayanand Medical college and Hospital, Ludhiana; over a period of 14 months. An individual lesion's viability post MWA will be assessed in accordance to LI-RADS treatment response algorithm, and overall patient's response to treatment by the mRECIST criteria at intervals of 6 weeks and 3 months post ablation.

Clinical Significance: Treatment of HCC has always been challenging for medical practitioners, especially in those who are poor surgical candidates. Ablation therapy is thence recommended in non resectable BCLC 0 and A patients with lesions <3 cm. In some studies, MWA has shown potential effectiveness in treating lesions between 3 - 5cm [1], however there is a lacuna of information on such a response in the Northern region of India, which this study strives to fill.

Keywords: Hepatocellular carcinoma, microwave ablation, loco-regional therapy, Interventional radiology.

(Signature) Candidate	(Signature) Co-supervisor	(Signature) Co-Supervisor	(Signature) Supervisor	(Signature) Principal

CERTIFICATE OF FACILITIES AVAILABLE

This is to certify that the facilities for work on the subject of thesis titled **"ASSESSMENT OF TREATMENT RESPONSE TO MICROWAVE ABLATION IN HEPATOCELLULAR CARCINOMA"** exist in the Department of Radiodiagnosis, DMC&H, Ludhiana and will be provided to the candidate. We will see that the data being included in the thesis is genuine and is collected by the candidate herself under our supervision and guidance.

Supervisor

Dr. Siddharth Prakash
Associate Professor
Department of Radiodiagnosis
DMCH, Ludhiana

Co-Supervisor

Dr. Ajit Sood
Professor & Head
Department of Gastroenterology
DMCH, Ludhiana

Dr. Chandan Kakkar
Associate Professor
Department of Radiodiagnosis
DMCH, Ludhiana

Head of the Department

Dr. Kavita Saggar
Professor & Head
Department of Radiodiagnosis
DMCH, Ludhiana

Place : _____

Date : _____

APPROVAL PROFORMA
BY
RESEARCH & ETHICAL COMMITTEE
DAYANAND MEDICAL COLLEGE & HOSPITAL, LUDHIANA

Name of candidate	DR. SHIVANI KHANT
Department	Radiodiagnosis
Topic of Thesis	ASSESSMENT OF TREATMENT RESPONSE TO MICROWAVE ABLATION IN HEPATOCELLULAR CARCINOMA
Likely date of appearing in PG examination	June 2023
Date of enrollment	26TH JUNE 2020
Name of Head of Department	Dr. Kavita Saggar
1) **Supervisor** 2) **Co-Supervisor(s)**	Dr. Siddharth Prakash Dr. Ajit Sood Dr. Chandan Kakkar
Signature of Members of Research Committee with Stamp	**Signature of Members of Ethics Committee with Stamp**
Dr. Harpreet Kaur (Professor & Head, Pathology)	Mr. R K Sharma (Legal Expert)
Dr. Jaspal Singh (Professor & Head, Surgery)	Dr. Ramit Mahajan (Associate Professor, Gastroenterology)
Dr. Dinesh Gupta (Professor & Head, Medicine)	Dr. Anu Sharma (Professor, Anatomy)
Dr. Sandeep Kaushal (Dean Academics & Professor & Head, Pharmacology)	Dr. Sandeep Kaushal (Dean Academics & Professor & Head, Pharmacology)
Dr. Gurpreet S Wander (Vice Principal)	Dr. Gurpreet S Wander (Vice Principal & Professor & Head, Cardiology)
	Dr. Gagandeep Singh (Secretary, Ethics Committee Professor & Head, Neurology)

Approved: Yes / No

Dr. Sandeep Puri
Chairperson
Research Committee

Approved: Yes / ~~No~~

Prof. Arvind Malhotra
Chairperson
Ethics Committee

BABA FARID UNIVERSITY OF HEALTH SCIENCES, FARIDKOT

PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

1	NAME OF THE CANDIDATE AND ADDRESS	DR. SHIVANI KHANT P. O. Box 400 Kisumu, Kenya, 40100.
2	NAME OF THE INSTITUTE	Dayanand Medical College and Hospital, Ludhiana.
3	COURSE OF STUDY AND SUBJECT	M. D. Radiodiagnosis
4	DATE OF ADMISSION OF COURSE	26th July 2020
5	TITLE OF THE TOPIC	ASSESSMENT OF TREATMENT RESPONSE TO MICROWAVE ABLATION IN HEPATOCELLULAR CARCINOMA

6. BRIEF RESUME OF THE INTENDED WORK

6.1 NEED FOR THE STUDY

The liver is the largest glandular organ of the human body and needless to say, it has a major role in maintaining metabolic functions, synthesis of proteins and production of biochemicals necessary for digestion and growth, detoxification of exogenous and endogenous substances such as drugs, xenobiotics, alcohol and viral infections. Chronic liver disease hence results as a series of bad sequels beginning with steatosis, hepatitis, cirrhosis, fibrosis, and later hepatocellular carcinoma.

Hepatocellular carcinoma is the most common primary liver neoplasm. It is the fifth highest cause of the global cancer burden, and is the second most leading cause of cancer related deaths [1]. The age adjusted incidence of HCC in India is 0.7 - 7.5 in men and 0.2 - 2.2 in women per 100,000 of population per year. The mortality rates of HCC in India are 6.8/100000 and 5.1/100000 in men and women respectively [2]. Moreover, the incidence rates of HCC are increasing, with more and more people presenting with chronic hepatitis C virus (HCV) infection, chronic hepatitis B virus (HBV) infection, alcoholic liver cirrhosis, and non-alcoholic fatty liver disease (NAFLD).

In developing counties such as India, there is an extreme insufficiency of data on HCC, with poor HCC surveillance in those already diagnosed with chronic liver disease. On a background of illiteracy and poverty, most people present much later during the course of the disease, making most cases of HCC unsuitable candidates for surgical resection or orthotopic liver transplant at the time of presentation; further increasing the need for early diagnosis and management by locoregional therapies.

The first line treatment for very early and early stage HCC as per the European Association for the study of Liver (EASL) guidelines is liver transplantation and resection.[3] However, when the patient is not a suitable surgical candidate; more than 80% of the cases [4]; according

to the Modified Barcelona Clinic Liver Cancer (BCLC) staging and treatment strategy, radiofrequency ablation is recommended for very early stage 0 (single lesion <2cm) and early stage A (single or 2-3 nodules <3cm) with preserved liver function and performance status (PS) 0 [5].

The American Association for the Study of Liver Disease (AASLD) [6] and Society of Intervention Radiology (SIR) [7] recommend percutaneous radiofrequency ablation for treatment of HCC in patients unsuitable for surgical resection with BCLC stage 0 and A.

With recent advances in ablation therapies, MWA shows similar effects as RFA and has gained more popularity among interventional radiologists. Both modalities cause thermal injury to the targeted tissue; MWA is based on electromagnetic heating while RFA generates heat by electric currents. This core difference in the principles of heat generation between the two modalities is the reason as to why MWA has a better edge in obtaining ablations zones when compared to RFA. The effects of RFA are therefore limited by the heat-sink effect and increased impedance of the ablated tissue. On the other hand, MWA gives a wider, more predictable necrotic ablation zone, using less heat in a shorter time. MWA is thence a better suited option for ablation of lesions in difficult anatomical sites and lesions next to vascular structures.

Owing to the advantages of MWA in very early and early stage of HCC, the potential effectiveness of microwave ablation in treating large tumors (size range of ≥ 3cm and <5cm); beyond the BCLC guidelines; is being explored in many recent studies [8,9]; however, very little data is available on its effectiveness in HCC patients in India.

This study intends to explore the therapeutic efficiency of MWA in HCC patients in the Northern region of India, thereby providing crucial data to clinicians in their approach to treating HCC. Not only do the clinicians and interventional radiologists strive to come up with the most suitable treatment option, they also face challenges in terms of scarcity of clinical resources and patient's financial capabilities to afford

the same. Thence, the results of this study will provide baseline data for the treating team, in curbing such challenges in future, and help in deciding upon the best practically suited approach of management for the patient’s betterment.

6.2 REVIEW OF LITERATURE

Orthotopic liver transplant and surgical resection are considered as the first-line treatment for very early stage 0 (single lesion <2cm) and early stage A (single or 2-3 nodules <3cm) HCC as per the EASL guidelines [3]. However, when the patient is not a suitable surgical candidate, Modified Barcelona Clinic Liver Cancer (BCLC) staging and treatment strategy recommends , radiofrequency ablation [5].

Percutaneous thermal ablation therapy is a minimally invasive procedure used in the treatment of hepatic tumors. Ablation therapy is gaining popularity among interventional radiologists and is considered a potential first-line therapy for small HCC lesions. Radiofrequency ablation (RFA) uses electric current in the RF range, delivered through a monopolar or multipolar electrodes and produces heat based cytotoxicity to the tissue in contact. Microwave ablation (MWA) on the other hand, uses electromagnetic energy to heat the surrounding tissue, which is less susceptible to heat sink effect, making it more advantageous to RFA in treating tumors in close proximity to blood vessels [10].

Earlier, before MWA gained popularity, RFA and tumor resection were used as the locoregional therapies of choice for treating very early and early HCC lesions. Several studies were done to compare the efficacies of RFA and surgical resection for these earlier stages of HCC.

Many studies show comparative results in treatment of early HCC with surgical resection and radiofrequency ablation. A study by Lü et al. (2006) demonstrated a complete tumor free rate of 100% with surgical resection, compared to 94.7% with radiofrequency ablation with local recurrence rate of 0 [11]. In a separate study, Chen et al. (2006) reported no statistically significant difference in overall survival (OS) in those treated for a solitary tumor <5cm with either surgical resection or RFA. The 1-, 2, 3-, and 4- year OS rates were 93.3%, 82.3%, 73.4%, 64.0% and 95.8%, 82.1%, 71.4%, 67.9% for surgical resection and RFA respectively [12].

MWA has started to gain more acceptance with recent advances in technology, as it gives a wider ablation zone in a shorter time compared to RFA, with a further advantage of less heat sink effect. A study by Kuang et al. (2007), which was conducted beyond the BCLC guidelines that recommends targeted lesions to be <3cm for MWA. The study reported complete response rates of 94% in small (≤3.0cm), 91% in intermediate (3.1cm-5.0cm) and 92% in large (5.1cm-8.0cm) sized liver tumors [13].

A study by Yin et al. (2009) similarly reported CR rates of tumor sizes 3.0cm-5.0cm to be 95.4% and tumor sizes 5.0cm-7.0cm to be 80%. On using both RFA and MWA to ablate HCC tumors sized 3.0cm-7.0cm, Yin et al. reported overall survival rates at 1-, 2-, 3-, and 5-year as 76%, 47%, 31% and 15% respectively. Median survival rates for RFA was 19 months compared to 30.3 months of MWA treated patients [14].

A study from China by Liang P. et al. (2009) reported survival rates of 1007 patients with primary liver cancer as 91.2% and 59.8% at 1- year and 5-year post MWA. The study documented a 5-year survival rate ranging from 29% to 68.6% for tumors size > 5.0cm treated with MWA [15].

Another multicentric Italian study by Liragi et al. (2012) performed MWA on 736 patients with 1037 HCC lesions, proved MWA as a high safety procedure with little major complication rates [16].

A study conducted by Liu et al. (2013) analysed effects of MWA on HCC lesions of varying sizes and reported complete response (CR) rates of 94.2% for 3cm-5cm tumor sizes, and 75% for tumors sized 5cm-8cm [17]. This study again stretched the 3cm upper limit of individual lesions that is recommended by BCLC guidelines for MWA of early HCC.

A Cochrane review (2017) was done comparing effects of RFA and surgical resection in early HCC by conducting four trials in 574 patients. There was no significant difference in in mortality rates between the two treatment modalities. The authors reported more serious adverse events in the resection group compared to the RFA

group, but reported a lower recurrence rate of HCC in the resection group than in the RFA group. Length of hospital stay was found to be more in the surgically treated patients [18]. On analysing different literature materials, RFA was found by EASL to be the most cost-effective therapy for very early HCC and early HCC [19].

Wei H et al. (2017) conducted a study on 19 HCC patients with tumors size ranging from 3.0cm - 9.5cm, who were treated with MWA . The study followed up the patients at 1-, 3-, 6- months post ablation, and evaluated the response using mRECIST criteria. From a total of 23 tumors, 8 tumors had Complete Response (CR), 10 tumors showed Partial Response (PR), 3 tumors had Stable Disease (SD), and 2 tumors had Progressive Disease (PD). The study reported an OS rate of 94.4%, 94.4% and 85.7% for 6- month, 1-year and 2-year follow up respectively. The study reported a survival benefit of years for tumors sized ≥3.0cm that were treated with MWA [20].

A study by Ma S. et al. (2017) retrospectively analysed 433 HCC patients, with lesions ≤ 10.0cm who received MWA. The study reported the efficacy of MWA after a one month interval of the treatment, and reported the following outcomes: initial complete ablation (CA) rate of 94.9 % in 411/433 patients. 22/433 with incomplete ablation, later received repeated treatment of MWA, and increased the complete ablation rate to 98.6% in 427/433 patients. The study reported a cumulative overall survival rate of 83.5%, 66.1%, and 58.7 % at 1-, 2-, and 3-year interval, respectively. The study concluded by expressing good tolerance of MWA in HCC patients, and proving high complete ablation rates in its sample group. They also expressed, multiple tumor number, tumor size >5cm, and serum AFP level >20ng/ml to be significant poor prognostic indicators of progression-free survival [21].

A study by Filippiadis DK et al. (2018) was conducted to analyse the efficacy of MWA in HCC lesions at difficult anatomical sites, such as tumors in close proximity to the heart, or at hilum of the liver, in the hepatic dome, or subcapsularly. The study reported a 2-year and 5-year survival rate of 92.3% and 72.11%, respectively. In conclusion,

they documented high efficacy and safety rates of MWA in difficult anatomical sites in lesions measuring <5.0 cm [22].

Darweesh SK and Gad AA (2019), conducted a study on effects of MWA on HCV- related hepatocellular carcinoma on fifty nine patients. They reported a complete ablation in 57 (96.6%) patients, with minor complication rate of 3.3%. Furthermore, the study showed no significant ablation rates when tumor sizes <3.0 cm and 3.0-5.0cm were compared. The study documented survival rates of 95.4% at 1 year and 69% at 2 years interval [23].

Biondetti P. et al (2020) conducted a study to identify the predictors of outcomes and complications of 74 HCC patients treated with MWA over a period of 2.5 years. On a one month follow up, incomplete response rate of 18.9%, local tumor progression rate of 13.5% and development of a new HCC lesion rate of 27% was reported. 48% of the patients were reported to have at least one complication, most of which were asymptomatic imaging findings that did not require any further interventions. These minor complications were observed in candidates with multifocal lesions, deranged coagulation profiles, ascites, portal vein thrombosis and other comorbidities [24].

A retrospective observational study conducted Gaia S. et al. (2021) compared the efficacy of RFA and MWA in achieving complete response in very early and early HCC patients with cirrhosis. The data showed not statistically significant difference in complete response rates of patients treated with RFA versus those treated with MWA. However, a sub-analysis of lesions measuring 2.1cm to 3.5cm, demonstrated a 5 times higher probability to achieve complete response rates in patients treated with MWA as compared to those treated with RFA [25].

The early dynamic changes in circulating tumor cells (CTCs) and the prognostic relevance following MWA and C-TACE (conventional transarterial chemoembolisation) in HCC patients was studied by Vogl TJ. et al. (2021). Pre-treatment CTCs were detected in 76% of the patients. In patients treated with MWA, the rates of CTCs was

significantly lower (0.4 CTCs/ml of blood, p = 0.013) compared to those treated with C-TACE (0.3 CTCs /ml of blood, p = 0.300). The study found no significant correlation between the locoregional therapies and the recurrence rate, however, it concluded by emphasizing on the tumoricidal effect of MWA on HCC [26].

6.3 AIMS AND OBJECTIVES OF THE STUDY

1. To assess the outcome of hepatocellular carcinoma lesions that are treated with microwave ablation.

7. MATERIALS AND METHODS

An observational prospective study will be conducted on patients undergoing MWA for radiologically proven HCC, at the Department of Radiodiagnosis, Dayanand Medical College and Hospital, Ludhiana; over a period of 14 months. An individual lesion's viability post MWA will be assessed in accordance to LI-RADS treatment response algorithm, and overall patient's response to treatment by the mRECIST criteria at intervals of 6 weeks and 3 months post ablation.

7.1 Source of Data

The study will include patients diagnosed with HCC who present to the Department of Radiology in Dayanand Medical College and Hospital, Ludhiana; prospectively over a period of 14 months, and who after thorough discussion of their clinical presentation with their primary clinician and interventional radiologist regarding their treatment options, undergo ultrasound guided microwave ablation for the treatment of HCC

7.2 METHOD OF COLLECTION OF DATA

Written consent will be obtained from each patient willing to participate in the study, after having explained the procedure in his/her vernacular language. A detailed clinical history will be documented of each patient's clinical profile, with special attention to the age of presentation, gender, alcohol history, background of non-alcoholic fatty liver disease (NAFLD), liver cirrhosis, history of Hepatitis C virus infection and history of Hepatitis B virus infection. The diagnosis of hepatocellular carcinoma will be based on contrast enhanced CT / MRI triphasic imaging evidence (homogenous arterial phase enhancement with washout in portal and delayed venous phase) with or without raised Alpha Fetoprotein levels (AFP) or based on trucut biopsy results of the lesion. The patients who are diagnosed with HCC and undergo ultrasound guided MWA as the therapeutic procedure of choice, will be included in this study.

INCLUSION CRITERIA:

The inclusion criteria for patients eligible for MWA and thence this study, will be as follows:

- No more than 3 tumors in each individual patient
- Tumor size ≤ 5.0cm
- Liver function status at Child-Pugh class A or class B [5]

Good coagulation profile, with International Normalized Ratio (INR) <1.5 and platelet count of >50,000/mm^3.

EXCLUSION CRITERIA:

The following patients will be excluded from the MWA therapy:

- Tumor size > 5.0 cm
- Presence of vascular invasion, distant metastasis, and lymph node involvement.
- Liver function status at Child-Pugh class C
- Insufficient patient data

Duration of Study

The study will span over a period of 14 months, including all patients who undergo ultrasound guided MWA in view of hepatocellular carcinoma at the Department of Radiology, Dayanand Medical College and Hospital, Ludhiana, during this time

Outcome:

Contrast enhanced CT or MRI will be performed on patients treated with MWA for HCC at 6 weeks and 3 months post microwave ablation to evaluate the therapeutic response. This will be assessed in terms of viability of individual lesions post MWA in accordance to the LI-RADS treatment response algorithm [27] and overall patient's response to the ablation, will be assessed in accordance to the mRECIST criteria [28]. The observations made shall be categorised as follows:

LI-RADS TREATMENT RESPONSE (LR-TR):

TREATMENT RESPONSE CATEGORY		CRITERIA
LR-TR Nonviable	Treated, probably or definitely not viable	No lesional enhancement OR treatment specific expected enhancement pattern.
LR-TR Equivocal	Treated, equivocally viable	Enhancement atypical for treatment specific expected enhancement pattern and does not meet criteria for probably or definitely viable.
LR-TR Viable	Treated, probably or definitely viable	Nodular, mass like, or thick irregular tissue in or along the treated lesion with any of the following: • Arterial phase hyperenhancement OR • Washout appearance OR • Enhancement similar to pre-treatment.

mRECIST CRITERIA:

TREATMENT RESPONSE CATEGORY	CRITERIA
Complete Response (CR)	Disappearance of the targeted lesions
Partial Response (PR)	At least a 30% decrease in the sum of the longest diameter of targeted lesions
Progressive Disease (PD)	20% increase in the sum of the longest diameter of the targeted lesion, or the appearance of one or more new lesions
Stable Disease (SD)	Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease

STATISTICAL ANALYSIS:

Data will be described in terms of range; mean ± standard deviation (± SD), frequencies (number of cases) and relative frequencies (percentages) as appropriate. All statistical calculations will be done using (Statistical Package for the Social Science) SPSS 21version (SPSS Inc., Chicago, IL, USA) statistical program for Microsoft Windows

7.3 DOES THE STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY.

No.

7.4 HAS ETHICAL CLEARANCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.3?

Attached herewith

REFERENCES

1. Izzo F, Granata V, Grassi R, Fusco R, Palaia R, Delrio P, et al. Radiofrequency ablation and microwave ablation in liver tumors: an update. The oncologist. 2019;24:e990.
2. Siddiqui MA, Siddiqui HH, Mishra A and Usmani A: Epidemiology of hepatocellular carcinoma. Int J Pharm Sci & Res. 2018;9:5050-59.
3. European association for the study of the liver. EASL-EORTC clinical practice guidelines: management of hepatocellular carcinoma. Journal Hepatol. 2012;56;908-943.
4. Poulou LS, Botsa E, Thanou I, Ziakas PD, Thanos L. Percutaneous microwave ablation vs radiofrequency ablation in the treatment of hepatocellular carcinoma. World J Hepatol. 2015;7;1054-63.
5. Llovet JM, Bru C, Bruix J. Prognosis of hepatocellular carcinoma: the BCLC staging classification. Semin Liver Dis. 1999;19:329-38.
6. Bruix J, Sherman M; American Association for the Study of Liver Diseases. Management of hepatocellular carcinoma: an update. Hepatology. 2011;53:1020-2.
7. Gervais DA, Goldberg SN, Brown DB, Soulen MC, Millward SF, Rajan DK. Society of Interventional Radiology position statement on percutaneous radiofrequency ablation for the treatment of liver tumors. Journal of Vascular and Interventional Radiology. 2009;20: 3-8.
8. Thamtorawat S, Hicks RM, Yu J, Siripongsakun S, Lin WC, Raman SS, et al. Preliminary Outcome of Microwave Ablation of Hepatocellular Carcinoma: Breaking the 3--cm Barrier?. Journal of Vascular and Interventional Radiology. 2016;27:623-30.
9. Yin XY, Xie XY, Lu MD, Xu HX, Xu ZF, Kuang M, et al. Percutaneous thermal ablation of medium and large hepatocellular carcinoma. Cancer. 2009;115:1914-23.

10. European Association For The Study Of The Liver. EASL clinical practice guidelines: management of hepatocellular carcinoma. Journal of hepatology. 2018;69:182-236.
11. Lü MD, Kuang M, Liang LJ, Xie XY, Peng BG, Liu GJ, et al. Surgical resection versus percutaneous thermal ablation for early--stage hepatocellular carcinoma: a randomised clinical trial. Zhonghua yi xue za zhi. 2006;86:801
12. Chen M S, Li J Q, Zheng Y, Guo R P, Liang H H, Zhang Y Q, et al. A prospective randomized trial comparing percutaneous local ablative therapy and partial hepatectomy for small hepatocellular carcinoma, Annals of surgery. 2006;243:321-8.
13. Kuang M, Lu MD, Xie XY, Xu HX, Mo LQ, Liu GJ, et al. Liver Cancer: Increased Microwave Delivery to Ablation Zone with Cooled--Shaft Antenna- Experimental and Clinical Studies !. Radiology. 2007;242:914-24.
14. Yin XY, Xie XY, Lu MD, Xu HX, Xu ZF, Kuang M, et al. Percutaneous thermal ablation of medium and large hepatocellular carcinoma. Cancer. 2009;115:1914-23.
15. Liang P, Wang Y, Yu X, Dong B. Malignant liver tumors: treatment with percutaneous microwave ablation--complications among cohort of 1136 patients. Radiology. 2009;251:933-40.
16. Livraghi T, Meloni F, Solbiati L, Zanus G, Collaborative Italian Group using AMICA system. Complications of microwave ablation for liver tumors: results of a multicenter study. Cardiovascular and interventional radiology. 2012;35:868-74.
17. Liu Y, Zheng Y, Li S, Li B, Zhang Y, Yuan Y. Percutaneous microwave ablation of larger hepatocellular carcinoma. Clinical radiology. 2013;68:21-6.
18. Majumdar A, Roccarina D, Thorburn D, Davidson BR, Tsochatzis E, Gurusamy KS. Management of people with early- or very early-stage hepatocellular carcinoma. Cochrane Database Syst Rev 2017;3:CD011650.
19. Cucchetti A, Piscaglia F, Cescon M, Colecchia A, Ercolani G, Bolondi L, et al. Cost-effectiveness of hepatic resection vs.

percutaneous radiofrequency ablation for early hepatocellular carcinoma. J Hepatol. 2013;59:300–7.

20. Wei H, Chivi S, Contractor S. Long-Term Survival of Large (≥ 3CM) Hepatocellular Carcinoma Treated with Microwave Ablation. Clin Oncol. 2017;2:1294.
21. Ma S, Ding M, Li J, Wang T, Qi X, Shi Y, et al. Ultrasound-guided percutaneous microwave ablation for hepatocellular carcinoma: clinical outcomes and prognostic factors. Journal of cancer research and clinical oncology. 2017;143:131-42.
22. Filippiadis DK, Spiliopoulos S, Konstantos C, Reppas L, Kelekis A, Brountzos E, et al. Computed tomography-guided percutaneous microwave ablation of hepatocellular carcinoma in challenging locations: safety and efficacy of high-power microwave platforms. International Journal of Hyperthermia. 2018;34:863-9.
23. Darweesh SK, Gad AA. Percutaneous microwave ablation for HCV-related hepatocellular carcinoma: Efficacy, safety, and survival. The Turkish Journal of Gastroenterology. 2019;30:445.
24. Biondetti P, Fumarola EM, Ierardi AM, Coppola A, Gorga G, Maggi L, Valconi E, Angileri SA, Carrafiello G. Percutaneous US-guided MWA of small liver HCC: predictors of outcome and risk factors for complications from a single center experience. Medical Oncology. 2020 May;37(5):1-9.
25. Gaia S, Ciruolo M, Ribaldone DG, Rolle E, Migliore E, Mosso E, Vola S, Risso A, Fagoonee S, Saracco GM, Carucci P. Higher Efficiency of Percutaneous Microwave (MWA) Than Radiofrequency Ablation (RFA) in Achieving Complete Response in Cirrhotic Patients with Early Hepatocellular Carcinoma. Current Oncology. 2021;28:1034-44.
26. Vogl TJ, Riegelbauer LJ, Oppermann E, Kostantin M, Ackermann H, Trzmiel A, et al. Early dynamic changes in circulating tumor cells and prognostic relevance following

interventional radiological treatments in patients with hepatocellular carcinoma. Plos one. 2021;16:e0246527.

27. Voizard N, Cerny M, Assad A, Billiard JS, Olivié D, Perreault P, et al. Assessment of hepatocellular carcinoma treatment response with LI-RADS: a pictorial review. Insights into imaging. 2019;10:1-22.
28. Lencioni R, Llovet JM. Modified RECIST (mRECIST) assessment for hepatocellular carcinoma. InSeminars in liver disease. Thieme Medical Publishers. 2010;30:52-60.

S.No._____

PROFORMA

ASSESSMENT OF TREATMENT RESPONSE TO MICROWAVE ABLATION IN HEPATOCELLULAR CARCINOMA

Date: _____

Biodata:

Name: _____

Age : _____ Sex : _____

MRD No: _____

Contact No: _____

Address: _____

Clinical History

Basic diagnosis: Normal liver CLD Cirrhosis

IF Cirrhosis:

Etiology: HCV HBV Alcoholic NASH

Family history of cirrhosis: Yes / No

IF HCV/HBV +

Viral load: Genotype:

Antiviral treatment: on treatment completed vaccinated

Viral status: response : present / absent

Ascites: Yes / No

Encephalopathy: Yes / No

Alcohol: YES/ NO Smoker: YES / NO Opium: YES/ NO

Presentation : Incidental pickup surveillance decompensated cirrhosis

Signature of Candidate **Signature of Supervisor**

S.No._____

GENERAL PHYSICAL EXAMINATION:

Vitals: HR _____ bpm

BP _____ mm/Hg

RR _____ cpm

SPO_2 _____ %

Pallor:

Oedema:

Jaundice:

Clubbing:

Cyanosis:

Investigations:

LFT	S. Bilirubin	mg/dl
	D. bilirubin	mg/dl
	SGOT	U/L
	SGPT	U/L
	T. Albumin	g/dl
	T. Proteins	g/dl
	Alk. Phosphate	U/L
AFP levels		
CBC	Hb	
	WBC	
	Platelets	
Coagulation Profile	PT / INR	
RFT	S. Creatinine	mg/dl
	S. Urea	mg/dl
	S. Na^+	mmol/L

CHILD - PUGH Score:
(T.bilirubin + INR + Albumin + Ascites + Encephalopathy)

MELD Score: (creatinine, bilirubin, INR)

Signature of Candidate

Signature of Supervisor

S.No._____

CT / MRI Findings:

IF Cirrhosis

Size

Liver

Spleen

Surface: Nodular Irregular

Left lobe hypertrophy:

Recanalization of Umbilical vein:

Vascular Thrombosis

Main PV Rt branch Lt Branch

SMV

Any other

IVC

Metastasis:

Ascites:

Any Collaterals

FNAC / BIOPSY result:

BCLC Stage:

Signature of Candidate **Signature of Supervisor**

S.No._____

Management:

Total number of MWA sittings: _____

	Lesion 1	Lesion 2	Lesion 3
Segment			
Size			
Arterial Enhancement			
Portal phase			
Venous phase			
MWA Ablation zone: Ablation time: Power:			

Signature of Candidate **Signature of Supervisor**

S.No._____

FOLLOW UP IMAGING (CECT / CEMR TRIPHASIC)			
	LESION 1	LESION 2	LESION 3
At 6 weeks interval Date:			
LI-RADS LR-TR Nonviable/equivocal/viable			
mRECIST Criteria (CR/PR/PD/SD)			
At 3 months interval Date:			
LI-RADS LR-TR Nonviable/equivocal/viable			
mRECIST Criteria (CR/PR/PD/SD)			
In case of death, the cause of death			

Signature of Candidate **Signature of Supervisor**

INFORMED PATIENT CONSENT

Date: _____

I.....D/o, W/o, S/o..... .....am willing to participate in the study **"ASSESSMENT OF TREATMENT RESPONSE TO MICROWAVE ABLATION IN HEPATOCELLULAR CARCINOMA"** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests and extra expenditure in any form, merely for the purpose of thesis is being carried out. I am free to opt out the study any time without assigning any reason.

....

Signature of the Witness Signature of the patient

Name:

Signature of Candidate **Signature of Supervisor**

मरीज अनुमति फार्म

तिथि _____

मैं _____ पत्नी/पुत्र/पुत्री _____

निवासी _____

इस शोधकार्य **"ASSESSMENT OF TREATMENT RESPONSE TO MICROWAVE ABLATION IN HEPATOCELLULAR CARCINOMA"** में भाग लेने के लिए सहमत हूँ। मैं इस शोधकार्य में भाग लेने के लिए अपनी स्वेच्छा से तैयार हूँ। मैं पुष्टि करता/करती हूँ की यह स्वीकृति देने के लिए मुझे कोई आर्थिक प्रलोभन नहीं दिया गया और न ही दबाव डाला गया है। मुझे इस शोधकार्य का उद्देश्य स्पष्ट कर दिया गया है और मुझे यह विश्वास है की यह विज्ञान और मानवता के लाभ के लिए है। मुझे इस शोधकार्य में होने वाले जोखिम के बारे में समझा दिया गया है और मेरी समझ में यह जोखिम बहुत मामुली है।

मैं इस शोधकार्य में भाग लेने के सम्बन्ध में किसी भी समय अपनी अस्वीकृति व्यक्त कर सकता/सकती हूँ और मेरे अस्वीकृति व्यक्त करने का मेरे इलाज पर कोई प्रभाव नहीं पड़ेगा।

_____

गवाह के हस्ताक्षर

नाम:

_____

रोगी के हस्ताक्षर/अंगूठे का निशान

नाम:

_____

अन्वेषक के हस्ताक्षर

_____

विद्यार्थी के हस्ताक्षर

ਮਰੀਜ਼ ਰਜ਼ਾਮੰਦੀ ਫਾਰਮ

ਮਿਤੀ_____

ਮੈ_____ਪਤਨੀ/ਪੁੱਤਰ/ਪੁੱਤਰੀ_____

ਵਾਸੀ _____

"ASSESSMENT OF TREATMENT RESPONSE TO MICROWAVE ABLATION IN HEPATOCELLULAR CARCINOMA" ਤੇ ਚਲ ਰਹੀ ਖੋਜ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਰਜ਼ਾਮੰਦ ਹਾਂ। ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਮੈ ਆਪਣੀ ਮਰਜ਼ੀ ਨਾਲ ਤਿਆਰ ਹਾਂ। ਮੈ ਇਹ ਦਸਣਾ ਚਾਹੁੰਦਾ ਹਾਂ/ ਚਾਹੁੰਦੀ ਹਾਂ ਕੇ ਇਹ ਰਜ਼ਾਮੰਦੀ ਦੇਣ ਵਾਸਤੇ ਮੈਨੂ ਕਿਸੇ ਵੀ ਤਰਾਂ ਦਾ ਲੋਭ-ਲਾਲਚ ਨਹੀ ਦਿੱਤਾ ਗਿਆ ਅਤੇ ਨਾ ਹੀ ਕੋਈ ਦਬਾ ਪਾਇਆ ਗਿਆ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਦਾ ਮਨੋਰਥ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਭਰੋਸਾ ਦਵਾਇਆ ਗਿਆ ਹੈ ਕੇ ਇਹ ਖੋਜ ਵਿਗਿਆਨ ਅਤੇ ਮਾਨਵਤਾ ਦੀ ਭਲਾਈ ਲਈ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਵਿਚ ਹੋਣ ਵਾਲੇ ਖਤਰੇ ਬਾਰੇ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਯਕੀਨ ਹੈ ਕੇ ਇਹ ਖਤਰਾ ਬਹੁਤ ਮਾਮੂਲੀ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਦਾ ਢੰਗ – ਤਰੀਕਾ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ।

ਮੈ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਬਾਰੇ ਆਪਣੀ ਰਜ਼ਾਮੰਦੀ ਕਿਸੇ ਵੀ ਸਮੇ ਵਾਪਸ ਲੈ ਸਕਦਾ ਹਾਂ/ ਸਕਦੀ ਹਾਂ ਅਤੇ ਮੇਰੀ ਰਜ਼ਾਮੰਦੀ ਵਾਪਸ ਲੈਣ ਦਾ ਮੇਰੇ ਇਲਾਜ ਤੇ ਕੋਈ ਅਸਰ ਨਹੀ ਹੋਵੇਗਾ।

_____
ਗਵਾਹ ਦੇ ਹਸਤਾਖਰ

ਮਿਤੀ_____

ਪਤਾ _____

_____
ਮਰੀਜ਼ ਦੇ ਹਸਤਾਖਰ

ਮਿਤੀ_____

ਪਤਾ _____

_____
ਨਿਰੀਖਕ ਦੇ ਹਸਤਾਖਰ

_____
ਸਿਖਿਆਰਥੀ ਦੇ ਹਸਤਾਖਰ